a deceased person, and it is later established that:

(i) the claimant was convicted of a felony or an act in the nature of a felony for intentionally causing that person's death; or

(ii) If the claimant was subject to the juvenile justice system, he or she was found by a court of competent jurisdiction to have intentionally caused that person's death by committing an act which, if committed by an adult, would have been considered a felony or an act in the nature of a felony;

(8) The claimant shows that it is to his or her advantage to select a later annuity beginning date and refunds, by cash payment or setoff, past payments applying to the period prior to the later beginning date, subject, however, to the provisions of subpart D of part 217 and § 218.9 of this chapter;

(9) The decision is incorrect because of a failure to apply a reduction, or the proper reduction, to the tier I component of an annuity;

(10) Except as is provided in § 261.4 of this part, the decision is incorrect for any reason and results in entitlement to an annuity in a case where if the decision were correct there would be no entitlement.

(d) Revision of the amount or payment of a separation allowance lump sum amount pursuant to section 6(e) of the Railroad Retirement Act is limited to 60 days from the date of notification of the award of the separation allowance lump sum payment.

§ 261.3 Change of legal interpretation or administrative ruling.

A change of legal interpretation or administrative ruling upon which a decision is based does not render a decision erroneous and does not provide a basis for reopening.

§ 261.4 Decisions which shall not be reopened.

The following decisions shall not be reopened:

(a) An award of an annuity beginning date to an applicant later found to have been in compensated service to an employer under part 202 of this chapter on that annuity beginning date and who is found not to be at fault in causing the erroneous award; provided, however, that this exception shall not operate to permit payment of benefits for any month in which the claimant is found to be engaged in compensated service.

(b) An award of an annuity based on a subsequently discovered erroneous crediting of months of service and compensation to a claimant where:

(1) The loss of such months of service and compensation will cause the applicant to lose his or her eligibility for an annuity previously awarded;

(2) The erroneously credited months of service do not exceed six months; and

(3) The annuitant is found not to be at fault in causing the erroneous crediting.

(c) An erroneous award of an annuity where the error is no greater than one dollar per month per annuity affected.

(d) An erroneous award of a lump sum or accrued annuity payment where the error is no greater than $25.00.

§ 261.5 Late completion of timely investigation.

(a) A decision may be revised after the applicable time period in § 261.2(a) or § 261.2(b) of this part expires if the Railroad Retirement Board begins an investigation into whether to revise the decision before the applicable time period expires and the agency diligently pursues the investigation to the conclusion. The investigation may be based on a request by a claimant or on action by the Railroad Retirement Board.

(b) *Diligently pursued* for purposes of this section means that in view of the facts and circumstances of a particular case, the necessary action was undertaken and carried out as promptly as the circumstances permitted. Diligent pursuit will be presumed to have been met if the investigation is concluded and, if necessary, the decision is revised within 6 months from the date the investigation began.

(c) If the investigation is not diligently pursued to its conclusion, the decision will be revised if a revision is applicable and if it is favorable to the claimant. It will not be revised if it would be unfavorable to the claimant.

§ 261.6 Notice of revised decision.

(a) When a decision is revised, notice of the revision will be mailed to the parties to the decision at their last known address. The notice will state the basis for the revised decision and the effect of the revision. The notice will also inform the parties of the right to further review.

(b) If a hearings officer or the three-member Board proposes to revise a decision, and the revision would be based only on evidence included in the record on which the prior decision was based, all parties will be notified in writing of the proposed action. If a revised decision is issued by a hearings officer, any party may request that it be reviewed by the three-member Board, or the three-member Board may review the decision on its own initiative.

§ 261.7 Effect of revised decision.

A revised decision is binding unless:

(a) The revised decision is reconsidered or appealed in accord with part 260 of this chapter;

(b) The three-member Board reviews the revised decision; or

(c) The revised decision is further revised consistent with this part.

§ 261.8 Time and place to request review of a revised decision.

A party to a revised decision may request, as appropriate, further review of the decision in accordance with the rules set forth in part 260 of this chapter.

§ 261.9 Finality of findings when later claim is filed on same earnings record.

If two claims for benefits are filed on the same record of compensation, findings of fact made in a decision in the first claim may be revised in determining or deciding the second claim, even though the time limit for revising the findings made in the fist claim has passed. However, a finding in connection with a claim that a person was fully or currently insured at the time of filing an application, at the time of death, or any other pertinent time, may be revised only under the conditions stated in § 261.2 of this part.

§ 261.10 Increase in future benefits where time period for reopening has expired.

If, after the time period for reopening under § 261.2(b) of this part has expired, new evidence is furnished showing a different date of birth or new evidence is furnished which would cause a correction in a record of compensation as provided for in part 211 of this chapter and, as a result of the new evidence, increased benefits would be payable, the Board will pay increased benefits, but only for the months following the month the new evidence is received.

§ 261.11 Discretion of the three-member Board to reopen or not to reopen a final decision.

In any case in which the three-member Board may deem proper, the Board may direct that any decision, which is otherwise subject to reopening under this part, shall not be reopened or direct that any decision, which is otherwise not subject to reopening under this part, shall be reopened.

Dated: December 14, 1995.

By authority of the Board.

For the Board

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 95–31059 Filed 12–20–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 94P–0390 and 95P–0241]

Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products. These changes are intended to benefit public health by encouraging manufacturers to use health claims and nutrient content claims that will assist consumers in maintaining a healthy diet. The agency's current regulations were issued in January of 1993 to implement the Nutrition Labeling and Education Act of 1990. This document proposes refinements to those regulations to allow additional synonyms for nutrient content claims without specific preclearance by the agency, permit health claims on certain foods that do not currently qualify because they do not contain 10 percent of certain required nutrients, permit the use of shortened versions of authorized health claims under certain circumstances, eliminate some of the required elements for health claims, and provide additional guidance for petitioners seeking exemption from the disqualification of some foods from bearing a health claim because they contain high levels of certain nutrients. FDA is proposing these amendments in response to petitions submitted by the National Food Processors Association (NFPA) and the American Bakers Association (ABA).

DATES: Written comments by March 20, 1996. The agency is proposing that any final rules that may issue based upon this proposal become effective on the date of publication.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 301–443–1751.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Center for Food Safety and Applied Nutrition (HFS–2), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. Among the more notable aspects of the 1990 amendments were that they confirmed FDA's authority to regulate nutrient content and health claims on food labels and in food labeling.

Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, provides that a product is misbranded if it bears a claim that characterizes the level of a nutrient of the type required to be included in nutrition labeling unless the claim uses terms that are defined and designated in regulations adopted by FDA and is made in accordance with all other regulatory requirements. Similarly, section 403(r)(1)(B) of the act provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with the requirements of the act.

The 1990 amendments instruct the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) to issue regulations defining nutrient content claims that characterize levels of nutrients in food. The 1990 amendments also instruct the Secretary (and, by delegation, FDA) to issue regulations authorizing health claims only if he or she determines,

> ''based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence'' (section 403(r)(3)(B)(i) of the act).

Section 403(r)(3)(B)(ii) and (r)(3)(B)(iii) of the act describe the information that must be included in any health claim authorized under the act. The act provides that the claim shall be an accurate representation of the significance of the substance in affecting the disease or health-related condition, and that it shall enable the public to comprehend the information and understand its significance in the context of the total daily diet. Section 403(r)(4)(A)(i) of the act also provides that any person may petition FDA to issue a regulation authorizing a nutrient content or health claim.

In addition, the 1990 amendments directed FDA to consider 10 disease-nutrient relationships as possible subjects for health claims.

B. FDA's Implementation of the 1990 Amendments

In the Federal Register of January 6, 1993 (58 FR 2066–2941), FDA adopted final rules that implemented the 1990 amendments to the act. Among those final rules, § 101.13 sets out general principles for nutrient content claims and provides for their use on food labels. Other regulations in subpart D of part 101 (21 CFR part 101) establish specific requirements for nutrient content claims. These regulations define specific terms such as ''free,'' ''low,'' ''good source,'' ''high,'' ''reduced,'' ''less (or fewer),'' ''more,'' and ''light'' or ''lite,'' and establish values for these terms for various nutrients. They also designate certain synonyms that can be used in place of these defined terms (58 FR 2302). In addition, § 101.69 establishes procedures for petitioning the agency to authorize additional nutrient content claims and provide for additional synonyms which, if authorized, will be listed in the relevant regulations (§ 101.69) (e.g., ''extra'' as a synonym for ''more'').

FDA also adopted final rules that implemented the health claims provisions of the act (58 FR 2478). Section 101.14 establishes general principles for health claims. This regulation prescribes the circumstances in which a substance is eligible to be the subject of a health claim (§ 101.14(b)), sets forth the standard in section 403(r)(3)(B)(i) of the act as the standard that the agency will apply in deciding whether to authorize a claim about a substance-disease relationship (101.14(c)), sets forth general rules on how authorized claims are to be made in food labeling (§ 101.14(d)), and establishes limitations on the circumstances in which claims can be made (§ 101.14(e)). The agency also adopted § 101.70, which established a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(f)).

At the same time, the agency announced its decisions regarding health claims on the 10 disease-nutrient

relationships specified in the 1990 amendments. Of the 10, FDA authorized health claims for calcium and osteoporosis (58 FR 2665); dietary lipids and cancer (58 FR 2787); sodium and hypertension (58 FR 2820); dietary saturated fat and cholesterol and risk of coronary heart disease (58 FR 2739); fiber-containing grain products, fruits, and vegetables and cancer (58 FR 2537); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (58 FR 2552); and fruits and vegetables and cancer (58 FR 2622). The regulations on general requirements for health claims and on the claims specified above became effective May 8, 1993.

In the Federal Register of January 6, 1993 (58 FR 2066), FDA also issued ''Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments,'' (the implementation final rule). The implementation final rule provided 30 days for interested persons to comment on technical issues arising in any of the final rules implementing the 1990 amendments. In the Federal Register of August 18, 1993 (58 FR 44020 to 44096), FDA published technical amendments to the final rules in response to the comments it received.

In the Federal Register of October 14, 1993 (58 FR 53254), FDA proposed to authorize the use of a health claim about the relationship between folate and the risk of neural tube defects on the labels or in labeling of foods in conventional food form and dietary supplements. This action was in response to provisions of the 1990 amendments and the Dietary Supplement Act of 1992 (Pub. L. 102–571). In the Federal Register of January 4, 1994 (59 FR 395), FDA announced that the proposed regulation to authorize use of the health claim about the association between folate and neural tube defects in food labeling was considered a final regulation for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances.

II. The Petition of the National Food Processors Association

The National Food Processors Association (NFPA) submitted a citizen petition dated October 25, 1994, requesting initiation of rulemaking for the adoption of amendments to the regulations governing nutrient content and health claims. This petition was assigned FDA Docket No. 94P–0390.

For nutrient content claims, NFPA requested specific amendments to §§ 101.13 and 101.65 allowing use of synonyms and implied nutrient content claims, without FDA preclearance, that are understood by consumers to have the same meaning as a defined term, where such claims are made in accordance with the requirements for the defined term, and the defined term also appears in the product's labeling.

NFPA also requested several amendments to the health claim regulations. Among other changes, NFPA requested that FDA permit the use of an abbreviated or implied health claim with a referral statement directing consumers to the complete claim elsewhere in labeling. Currently, all required information must appear in one place without other intervening material.

It also requested that health claims be permitted for foods with levels of nutrients that FDA had determined increase the risk of other diseases to the general population. Among the general requirements for health claims, FDA established in § 101.14(a)(5) levels of total fat, saturated fat, cholesterol, and sodium in a food above which the food is disqualified from making a health claim. These are identified as ''disqualifying nutrient levels.'' In its petition, NFPA suggested that FDA amend the regulation so that a food with a nutrient at a disqualifying level would be prohibited from making a health claim only if the nutrient is directly and adversely associated with the disease to which the claim refers. Absent such an association, NFPA requested that the presence of a nutrient above a threshold level not disqualify a product from bearing a health claim but instead require disclosure of that fact in labeling.

Finally, NFPA requested an amendment to § 101.14(e)(6), which prohibits a food in conventional food form from bearing a health claim unless the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition (the ''10 percent nutrient contribution requirement''). NFPA requested that this prohibition be replaced by a requirement that any food bearing a health claim that refers to an added nutrient disclose the fact of that nutrient addition in labeling.

FDA issued a letter on May 11, 1995, granting most of the requests to initiate rulemaking on the foregoing aspects of the petition (hereinafter referred to as the May 11, 1995, letter). However, the agency denied certain aspects of NFPA's petition, including NFPA's request that FDA change the levels in § 101.14(a)(5) from disqualification levels to disclosure levels. Although the agency recognized that it has the authority under section 403(r)(3)(A)(ii) of the act to exempt any claim from the disqualifying nutrient levels if it finds that the claim would ''assist consumers in maintaining healthy dietary practices,'' the agency concluded that a generic change in its regulations would not be consistent with the underlying goals of the NLEA.

FDA acknowledged, however, that disclosure rather than disqualification may be appropriate under certain circumstances. The agency said it will seek more limited criteria to define the conditions under which disclosure rather than disqualification could be permitted.

III. The Petition of the American Bakers Association

A citizen petition, dated July 27, 1995, was submitted to FDA by the ABA (Docket No. 95P–0241/CP 1), requesting that FDA amend, among other things, the regulatory provision in § 101.14(e)(6) to permit enriched cereal-grain products that conform to the standards of identity in part 136, 137, or 139 (21 CFR part 136, 137, or 139), and bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard, to bear health claims. The petition specifically requested that FDA amend § 101.14(e)(6) to read:

> Except for dietary supplements, enriched grain products that conform to a standard of identity in part 136, 137, or 139, and bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard, or where provided for in other regulations in part 101, subpart E.

In the alternative, ABA suggested that the agency expand the list of qualifying nutrients to include complex carbohydrates, niacin, or thiamin or allow the 10 percent nutrient contribution requirement to apply to all foods for which the summation of the Daily Value of the applicable nutrients is 10 percent rather than requiring that the 10 percent be based on a single serving.

Because of the similarities in the NFPA and ABA petitions regarding the 10 percent nutrient contribution and health claims, FDA is responding to part of the ABA petition in this document, which implements FDA's May 11, 1995, letter response to the NFPA petition. Other issues raised in the ABA petition will be handled separately.

IV. The Proposals

As the petitioners have requested, the agency is reconsidering its position on several of the issues raised in the NFPA and ABA petitions. The agency is well within its legal authority to reconsider the issues in the NFPA petition and propose changes to the current food labeling regulations. ''An agency may always change its mind and alter its policies.'' (See *Conference of State Bank Examiners* v. *Office of Thrift Supervision*, 792 F. Supp. 837, 845 (D.D.C. 1992)). While the burden is on the agency to justify the change from the status quo, that justification need not consist of an affirmative demonstration that the status quo is wrong. The agency need only supply ''a reasoned analysis for the change.'' (See *Center for Auto Safety* v. *Peck*, 751 F.2d 1336, 1349 (D.C. Cir 1985) (citing Motor *Vehicle Mfrs. Ass'n* v. *State Farm Mutual*, 463 U.S. 29, 41, 103 S.Ct. 2856, 2865–2866 (1983))). The agency can justify its departure from past policy ''with reference to the objectives underlying statutory scheme it purports to construe.'' (See *Simmons* v. *I.C.C.*, 829 F.2d 150, 156 (D.C. 1987)).

One of the primary purposes of the 1990 amendments was to educate consumers about healthful dietary practices. The legislative history states, ''Health claims supported by significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet'' (Ref. 1).

If the current regulations hinder food companies who want to use one of the FDA-authorized claims, as NFPA has alleged, this public health objective will be frustrated. As the agency has stated, if valid health claims are not being used, ''there is a cost imposed on society in that some valuable information may not be conveyed to consumers'' (58 FR 2927 at 2940). Consumers cannot change their dietary practices if they do not have the necessary information.

The agency is pleased that many food companies are using the health claims on the labels of their products. While the agency has not done an extensive survey, FDA notes that dozens of health claims have appeared on products such as cereal, cookies, frozen dessert bars, egg products, and frozen vegetables. Nonetheless, the agency is concerned that health claims are not being used as extensively as they could be, despite the fact that many foods qualify for such claims.

FDA also notes that food companies are submitting petitions seeking approval of new claims. Since the final regulations have been published, the agency has received two such petitions, one regarding sugar alcohols and dental caries and one regarding oat products and coronary heart disease. A proposed regulation to authorize a health claim regarding sugar alcohols and dental caries was published in the Federal Register on July 20, 1995 (60 FR 37502) (hereinafter referred to as the sugar alcohols proposal). The agency expects to complete in the very near future its evaluation of the petition regarding oat products and coronary heart disease.

Accordingly, the agency is proposing changes to the regulations regarding the use of synonyms for nutrient content claims, the 10 percent nutrient contribution requirement for health claims, the use of abbreviated health claims, the specific requirements for individual health claims, and disqualifying levels for health claims to facilitate additional use of these claims.

A. Synonyms in Nutrient Content Claims

Section 403(r)(1)(A) and (r)(2) of the act state that claims that either expressly or by implication characterize the level of a nutrient (nutrient content claims) may be made in the label or labeling of a food only if the characterization of the level made in the claim uses terms that are defined in regulations of the agency. Based on these provisions, the agency has defined expressed claims as any direct statement about the level (or range) of a nutrient in the food (§ 101.13(b)(1)). In addition, it has defined implied claims as nutrient content claims that describe the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran'') (§ 101.13(b)(2)(i)) or that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an expressed claim or statement about a nutrient (e.g., ''healthy, contains 3 grams of fat'') (§ 101.13(b)(2)(ii)).

The agency has specifically defined a number of expressed nutrient content claims (''free,'' ''low,'' ''reduced,'' ''light,'' ''good source,'' ''high,'' and ''more'') and provided for their synonyms, e.g., ''no,'' ''little,'' ''contains,'' and ''rich in.'' The agency also provided for certain implied nutrient content claims (§ 101.65(c) and (d)). Finally, the agency has defined the implied nutrient content claim ''healthy'' (§ 101.65(d)(2)).

The agency considered the use of additional synonyms for the defined terms in the 1993 nutrient content claims final rule (58 FR 2302 at 2320). At that time the agency provided for a limited number of specific synonyms and declined to provide for either long lists of synonyms or conditions for use of unevaluated terms. The agency concluded that permitting additional synonyms to be used in conjunction with either a defined claim or a disclosure statement explaining the synonym's intended meaning would not assist consumers in maintaining healthy dietary practices (58 FR 2302 at 2320). The agency stated that there is no provision in the act that allows for the use of undefined synonyms in the absence of action by the agency. Because of time constraints, in developing the final regulations FDA was unable to fully study the suggested schemes for use of terms without preclearance to determine whether a scheme could be devised that would constitute approval by the agency without preclearance of each term.

The agency also considered but rejected (58 FR 2302 at 2373) the suggestion that implied claims that are defined on the label be permitted. The agency did provide for certain implied claims on products that meet the definition for certain expressed claims and gave specific examples of some of these claims in the preamble (58 FR 2302 at 2374) and in the regulations (§ 101.65(c)(3)) (e.g., ''high in oat bran'' for foods that are a good source of fiber; ''no oil'' for fat free foods).

In the October 25, 1994, petition, as stated above, NFPA requested that the agency reconsider allowing synonyms and implied nutrient content claims to be used without FDA preclearance under certain circumstances. NFPA maintained that FDA's strict interpretation and application of the 1990 amendments totally frustrated the achievement of the various statutory goals of improving consumer education about diet and health and thereby reducing the incidence of diet-related diseases.

NFPA argued that, because the regulations sharply limit the terminology that can be used to make nutrient content claims for food products and require ''premarket clearance'' of terminology that FDA has not specifically authorized by regulation, the regulations ban a host of truthful and nonmisleading labeling statements. The petitioner requested that FDA propose amendments that would permit nonmisleading terms or statements that are reasonably understood by consumers to be synonyms of a term defined in subpart D of part 101 to be used in product labeling when the defined term also is used in the labeling. Requesting similar amendments for implied claims, NFPA

stated that such amendments would ensure that claims characterizing the level of a nutrient in a food are truthful and nonmisleading but would give manufacturers greater freedom to construct such labeling messages creatively.

In its May 11, 1995, response, FDA recognized that there may be some merit to the argument that more latitude in the use of truthful, nonmisleading nutrient content claims may assist consumers in maintaining healthy dietary practices because greater flexibility would provide the food industry with an increased incentive to develop more healthful products. Permitting synonyms for defined terms to be used on product labels without specific authorization for the particular synonyms has the potential to provide the industry with a greater variety of ways to convey nutrient information to the consumer because the nutrient content claims on the label would not be restricted to a finite list of terms that can only be expanded by filing an appropriate petition. This approach could facilitate the industry's efforts to arrive at terms that not only appropriately describe the nutrient level in a food but also effectively catch the attention of the consumer.

In its May 11, 1995, letter, the agency noted that while a plethora of uncontrolled terms would confuse consumers by diminishing the usefulness of clearly defined and limited terms, NFPA's ''anchoring'' concept, if properly implemented, could offer the possibility of increasing the available terms without confusing consumers. The agency stated that it was granting NFPA's petition to initiate rulemaking on the use of additional synonyms anchored to specifically authorized terms.

Consequently, the agency is proposing to add new paragraph (r) to § 101.13, which provides that synonyms may be used in labeling in accordance with one of two provisions. First, proposed § 101.13(r)(1) reflects the fact that a term may be used as a synonym when the agency has specifically listed it as a synonym for a defined term in one of the regulations listing authorized nutrient content claims in subpart D of part 101 (''listed synonym''). FDA included a number of synonyms in the regulation that it adopted as part of the 1993 nutrient content claims final rule. It has also adopted synonyms as a result of a petition filed in accordance with § 101.69(n). Additional synonyms may be added to FDA's regulations following this procedure. Second, FDA is proposing in § 101.13(r)(2) to authorize the use of synonyms that are not specifically listed by name in the regulations in subpart D of part 101, part 105, or part 107 (21 CFR part 105 or part 107) (''unlisted synonyms'') but are used in labeling in accordance with the labeling requirements set out in this provision.

Specifically, in § 101.13(r)(2), the agency is proposing a number of requirements to ensure that the use of unlisted synonyms will not confuse or mislead consumers. In particular, FDA is proposing in § 101.13(r)(2)(i) to require that an unlisted term be reasonably understood by consumers to be a synonym of a term defined in subpart D of part 101, part 105, or part 107. Such an understanding is necessary because the agency has, for example, defined the terms ''high'' and ''good source'' to represent two different levels of a nutrient.

Consumers can reasonably be expected to understand that ''without any [nutrient]'' is the same as ''free of [nutrient],'' and that ''not much'' of a nutrient is, in common usage, synonymous with ''low'' for that nutrient since ''not much'' implies that some but not a lot of the nutrient is present. Other ''synonyms'' however, may not be so clear. It is important, therefore, that the use of unlisted synonyms that FDA is proposing to authorize under § 101.13(r)(2) be clear and unambiguous to consumers regarding the levels to which they apply. Without such clarity, consumers may be confused as to the nutrient content of the food bearing the claim. Thus, regardless of the prominent use of a listed term or other explanatory information discussed below, terms that are not clearly understood by consumers to be synonymous with specific listed terms may still be misleading and misbrand the food under both section 403(a) and section 403(r)(1)(A) of the act.

Further, the agency is concerned that different manufacturers might use the same term but anchor it to different nutrient content claims. For example ''plenty of fiber'' might be anchored to ''good source'' on one product label and ''high'' on another. In this event, the agency reserves the right to call for petitions to define the term by regulation or to define the term on its own initiative.

The agency agrees with NFPA that, in addition to considering the words of the individual claim, it is important to consider the meaning of the unlisted synonym in the context of the entire product label. It is possible, for instance, that other statements such as other nutrient content claims on the label or in labeling could establish a context in which the unlisted synonym would be misleading. Section 403(a) of the act states that a food is misbranded if it bears any labeling statement that is false or misleading in any particular. Therefore, proposed § 101.13(r)(2)(i) requires that the unlisted synonym not be misleading in the context of the entire label.

The agency seeks comments as to whether further requirements should be imposed to ensure that an unlisted term is truly synonymous with a listed term. For example, FDA seeks comments as to whether it should require companies to have data in their files demonstrating that consumers understand the unlisted term to be synonymous with the listed term in question as a condition for the use of the unlisted terms. In addition, the agency seeks comments on why, if it includes such a requirement, it should not also require that such data be available for review by regulatory officials.

As stated above, for any term used as a synonym authorized under proposed § 101.13(r)(2) not to be misleading, the defined term for which it purports to be a synonym would have to be clear to the consumer. Proposed § 101.13(r)(2)(ii)(A) will require that the listed term appear prominently and conspicuously on the label.

Proposed § 101.13(r)(2)(ii)(A)(*1*) requires the listed term appear immediately adjacent to (with no intervening material) the most prominent (as defined in § 101.13(j)(2)(iii)) use of the unlisted synonym. The agency tentatively concludes that having a listed term immediately adjacent to the most prominent use of each such unlisted synonym will help to ensure that consumers understand the claim that is being made and thus to ascertain the level of the nutrient that the food purports to contain.

The agency tentatively concludes that it is not sufficient for the listed term to appear anywhere on the label, as suggested in the NFPA petition. Such a scheme would not guarantee that the unlisted synonym is read in conjunction with a listed term and would hinder the consumer from ascertaining the level of the nutrient that the food purports to have. For example, with such a provision, the unlisted synonym authorized under § 101.13(r)(2) could be very large and prominent, and the listed term could be a part of the fine print (i.e., in small print that is in sentence or paragraph form elsewhere on the label). Although such defining information may be read by consumers at some point, it would be unlikely to be fully read and comprehended at the same

time as the unlisted term and thus would not make clear to the consumer that the two statements are synonymous.

The agency's proposal is consistent with section 403(f) of the act which deems a food to be misbranded if any word, statement, or other information required by the act to appear on the label or labeling is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Section 403(f) of the act necessitates placement of the listed term on the label so that it is likely to be read and understood, and thereby to eliminate any ambiguity as to the meaning of the unlisted synonym. Allowing the listed term to be anywhere on the label that the manufacturer chooses would not ensure that this requirement is met.

There are a number of precedents for requiring clarifying information in labeling to be adjacent to the text that it clarifies. For example, § 101.3(e) requires that the word ''imitation'' precede the name of the food imitated; the term ''artificial'' is required by § 101.22(i)(1)(i), (i)(1)(ii), and (i)(3) to be adjacent to the name of the flavor; and § 102.5(b)(2) (21 CFR 102.5(b)(2)) requires that if the percentage of a characterizing ingredient is required to be included in the common or usual name of the food, it must be adjacent to the name of the food. Further, several aspects of the nutrient content claims regulations require that clarifying statements such as the referral statement, ''See [side] panel for nutrition information'' (§ 101.13(g)); the disclosure statement, ''See [side] panel for information about [sodium] and other nutrients'' (§ 101.13(h)); the percentage reduction and identity of the reference food for a relative claim (§ 101.14(j)(2)(ii)); and other clarifying information about the food in relation to the claim, e.g., § 101.13(i)(2) and (p)(2), be immediately adjacent to the claim to which the statement pertains.

As with accompanying information for relative claims (i.e., percent reduction in the nutrient and identity of the reference food (§ 101.13(j)(2)(i) through (j)(2)(iii)), the agency considers the presence of a listed term to be necessary to ensure that the claim is understood by, and is not misleading to, consumers. However, as with accompanying information, it recognizes that to require that this information be included each time an unlisted synonym is used may overburden the label. Consequently, as with relative claims, the agency is proposing to require only that the defined term or listed synonym be placed immediately adjacent to the most prominent declaration of each unlisted synonym. Because of the similar purposes of the two requirements, the agency believes that the provisions in § 101.1(j)(2)(iii) for determining the order of prominence of relative claims are also appropriate for determining the order of prominence of presentations of an unlisted synonym. The order of prominence for relative claims is: (1) A claim on the principal display panel adjacent to the statement of identity, (2) a claim elsewhere on the principal display panel, (3) a claim on the information panel, or (4) a claim elsewhere on the label or labeling.

The agency is proposing in § 101.13(r)(2)(ii)(A)(2) that the listed term be at least half as prominent as the unlisted synonym. If it adopts these changes, FDA will evaluate prominence using type size, style, and color. In the past, FDA has required certain clarifying information to be in type at least half the size of that of the statement it is clarifying. For example, when the term ''light'' is used to describe a physical or organoleptic property of a food (e.g., ''light in color''), the clarifying information ''in color'' is required to be at least half the type size as the word ''light'' (§ 101.56(e)(2)). Similarly, when the term ''light'' is used on a meal type product to describe a nutrient reduction, a clarifying statement as to whether the food is ''low in calories'' or ''low in fat'' is required and must be at least half the size of the term ''light'' (§ 101.56(d)(1)(ii)). Further, § 102.5 requires that the percentage declaration of a characterizing ingredient or component be no less than half the height of the largest type appearing in the common or usual name when it has a material bearing on the nature of the product. Further, this information must appear in bold-faced type. As a final example, § 101.13(f) requires that any nutrient content claim not be more than two times larger than, and not unduly prominent in type style compared to, the statement of identity. All of these provisions are examples of requirements where clarifying information must be at least half as large or prominent as the statement that it is clarifying.

FDA is proposing section 101.13(r)(2)(ii)(A)(*1*) and r)(2)(ii)(A)(*2*) to ensure that the combination of unlisted and listed terms that appear on a food label are understood by consumers to be making a single claim. This understanding is crucial because the act requires that a nutrient content claim be made ''only if the characterization of the level made in the claim *uses terms which are defined in regulations* * * *.'' (Section 403(r)(2)(A)(i) of the act (emphasis added).) In its petition, NFPA argues that there is nothing in the act that defines a claim to mean individual label statements—as opposed to the overall message conveyed by labeling for a product. The petition stated that, in NFPA's view, a ''claim'' is properly viewed under the statute as referring to the message about the level of a particular nutrient in the food conveyed in the context of the entire product labeling. NFPA maintained that, while the labeling should include terms defined by FDA, other synonyms or implied statements concerning the nutrient should be viewed as components of the single labeling claim. FDA tentatively concludes that the use of unlisted synonyms in the manner proposed will ensure that consumers understand them to be part of a single nutrient content claim that uses terms defined by regulation. As stated in its May 11, 1995, letter to NFPA, however, the agency cannot finalize this rule unless it receives evidence demonstrating that consumers understand the terms used in this way.

FDA also recognizes that there may be some labels on which the listed term is significantly more prominent than an unlisted synonym. This would be the case, for example, if the listed term was made in a ''burst'' or in the statement of identity and the unlisted synonym was used in a paragraph in smaller sized type. Such usage might occur if a manufacturer wanted to use a variety of ways to express the level of a nutrient in a discussion about the food. The agency tentatively finds that, in this case, the level of the nutrient described by the listed term would be clearly understood, and additional clarification next to the smaller print on the same label would not be necessary. Therefore, FDA is proposing in § 101.13(r)(2)(ii)(B) that if the listed term is more than twice as prominent on a label as the listed synonym, such that the claimed nutrient level is clearly understood, e.g., a bold faced listed term versus an unlisted synonym used only in a paragraph in smaller sized type, the listed need not be placed adjacent to the unlisted synonym. The agency requests comment on whether this approach is consistent with a nonmisleading label.

The agency is also providing in proposed § 101.13(r)(2)(iv) that a listed term may not be used with an unlisted synonym to form a new term, e.g., extra low, extra high, especially good source, or great source. In its review of food

labels before the passage of the 1990 amendments, the Institute of Medicine (IOM) stated that consumers were confused by the plethora of terms on food labels and recommended that definitions of nutrient levels for label claims be severely restricted (Ref. 2). The IOM recommended that four levels be defined for explicit claims: Low, very low, high and very high or their equivalents. The agency has essentially done just that in defining, ''low,'' ''free,'' ''good source'' and ''high.'' With the use of unlisted synonyms, the agency is concerned that there may be instances when the use of unapproved modifiers for these terms (e.g., ''extra low,'' ''extra high,'' ''especially good source,'' ''great source'') would confuse consumers by unjustifiably suggesting that there is a distinction between the listed term with and without the modifier. To avoid this confusion, the agency tentatively concludes that it is necessary to prohibit the use of claims that consist of a term that modifies an existing listed term.

In the course of developing the definitions and other requirements for the use of nutrient content claims, the agency made a diligent effort to determine the various meanings and requirements of the nutrient content claims it defined. In some cases the agency determined that, in order for the label not to be misleading, it was necessary for certain additional information to be conveyed to consumers along with the claim. This information included referral or disclosure statements (required by the statute), additional label statements such as accompanying information for foods bearing relative claims (§ 101.13(j)(2)), and other statements such as ''not a sodium free food'' on a food bearing an ''unsalted'' claim that was not ''sodium free'' (§ 101.61(c)(2)(iii)). Just as this information is necessary for a listed term not to be misleading and for a label bearing such a claim to provide full and relevant information to the consumer, the agency tentatively concludes that such additional information is equally important and necessary when unlisted synonyms are used. Consequently, the agency is proposing in § 101.13(r)(2)(iii) to require that unlisted synonyms be used in conformance with all of the requirements for the use of the listed terms.

The petitioners also requested that the agency permit the use of unlisted synonyms with implied claims such as terms, statements, or symbols. As with unlisted synonyms, FDA tentatively finds that this concept may have some merit. However, the agency points out that implied claims that are consistent with a listed term may currently be used on a label. Therefore, the agency is not proposing further provisions for the use of implied nutrient content claims.

B. Section 101.14(e)(6): The 10 Percent Nutrient Contribution Requirement

In the Federal Register of January 6, 1993, FDA published a final rule entitled ''Food Labeling: General Requirements for Health Claims for Food'' (58 FR 2478) (hereinafter referred to as the 1993 health claims final rule). Among other things, this rule requires that, to be eligible to bear a health claim, a food other than a dietary supplement contain 10 percent or more of the Daily Value (DV) for vitamin A, vitamin C, iron, calcium, protein, or fiber, before any nutrient addition (§ 101.14(e)(6)). As explained in that document, FDA concluded that such a requirement was necessary to assure that the value of health claims would not be trivialized or compromised by their use on foods of little or no nutritional value. Furthermore, such a requirement responded to Congress's intent that health claim provisions consider the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus, foods bearing health claims should be consistent with current dietary guidelines. Furthermore, the agency concluded that fortification of foods of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading, especially if foods such as confections, soda, and sweet desserts are fortified to qualify for a health claim, because such foods have been cited in dietary guidance as those that should be used sparingly.

In the Federal Register of August 18, 1993 (58 FR 44036), FDA published technical amendments to the health claim regulations in response to comments that the agency received on the implementation final rule (hereinafter referred to as the 1993 health claims technical amendment). One of the comments stated that if a health claim petition were submitted for the claim ''useful only in not promoting tooth decay,'' virtually none of the sugar-free products on the market would be eligible to bear the claim because of the 10 percent nutrient contribution requirement.

In the 1993 health claims technical amendments, FDA acknowledged that certain food products of limited nutritional value that have been specially formulated relative to a specific disease condition, such as dental caries, may be determined to be appropriate foods to bear a health claim. The agency commented that its intention was to deal with such situations within the regulations authorizing specific health claims. Therefore, FDA amended § 101.14(e)(6) to state that:

> Except for dietary supplements not in conventional food form or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

The terminology ''not in conventional food form'' was subsequently deleted in the final rules pertaining to health claims for dietary supplements published in the Federal Register on January 4, 1994 (59 FR 395).

The sugar alcohols proposal proposes such an exemption from the 10 percent nutrient contribution requirement.

Following publication of the health claims final rule, two trade associations—NFPA and the ABA—submitted petitions to FDA requesting that the agency revise the general requirements for health claims and reconsider its decision regarding the 10 percent nutrient contribution requirement. The NFPA petition argued that the 10 percent nutrient contribution requirement precludes truthful, nonmisleading health claims because it sets an arbitrary nutritional contribution a food must make to the diet to qualify for any claim. Consequently, NFPA argued, the 10 percent nutrient contribution requirement prohibits some common fruits, vegetables, and other wholesome and nutritious foods from making health claims. While NFPA agreed that a food bearing a health claim should contain levels of the nutrient consistent with the health claim, it contended that the lack of significant levels of other nutrients should not prevent a food from bearing a health claim. NFPA argued that if other nutrient levels are deemed to be material with respect to consumers' understanding of a health claim, then such levels should be disclosed in the Nutrition Facts panel.

Furthermore, NFPA contended that the 1993 health claims final rule precludes truthful, nonmisleading claims because it prohibits a food from satisfying the 10 percent nutrient contribution requirement through fortification. NFPA stressed that even though fortification of a food to support a health claim is material information that should be disclosed in labeling, added and indigenous nutrients are equally nutritious, and, therefore,

prohibiting fortified foods from bearing a health claim is not justified.

NFPA requested that FDA amend § 101.14(e) by revoking the requirement that foods bearing a health claim contain 10 percent of the DV of vitamin A, vitamin C, calcium, protein, iron, or fiber before any nutrient addition, so that fruits, vegetables, and other nutritious foods could bear health claims.

The ABA petition did not request that the agency revoke the 10 percent nutrient contribution requirement. Rather, it requested that FDA modify the 10 percent nutrient contribution requirement to permit health claims on certain enriched grain products. ABA contended that while some enriched breads might meet the 10 percent nutrient contribution requirement for fiber, most enriched grain products cannot meet the 10 percent nutrient contribution requirement for any of the six listed nutrients because they are precluded by the standards of identity from containing 10 percent of the six listed nutrients. ABA also stated that the standards of identity require specific nutrient addition at levels that were established by FDA as optimal for reducing the risk of certain diet-related diseases. These foods, in fact, have been used for many years to improve the nutrition of U.S. consumers and to reduce the risk of diet-related diseases. Therefore, ABA contended that these foods are precisely the kinds of foods that should be permitted to bear health claims.

ABA argued that the 10 percent nutrient contribution requirement was obviously not intended to apply to foods that conform to the standards of identity for enriched grain products because it precludes virtually all enriched grain products from bearing health claims. It contended that this exclusion is inconsistent with the basis of the health claims because these foods are not only beneficial in reducing the risk of diet-related diseases but, more importantly, are also recommended in current dietary guidelines as foods whose consumption should be increased to maintain a balanced and healthful diet. The petition noted that the Food Guide Pyramid recommends that 6 to 11 servings of grain products be consumed per day. ABA contended that this recommendation demonstrates the importance of including these foods in the diet. ABA argued that the 10 percent nutrient contribution requirement has had the unintended effect of precluding foods that FDA concluded could appropriately bear a health claim from bearing the claim. Thus, ABA requested that the agency amend § 101.14(e) to exempt from the 10 percent nutrient contribution requirement enriched grain products that conform to a standard of identity in part 136, 137, or 139, and bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard.

In the alternative, ABA suggested that the agency expand the list of nutrients that must be present at 10 percent to include complex carbohydrates, niacin, or thiamin. Such action, the petition explained, would permit enriched grain products to bear health claims because these products are a significant source of such nutrients.

As a second alternative, ABA suggested that FDA amend the 10 percent nutrient contribution requirement to allow it to apply to a daily consumption of grain products rather than to the nutrient profile of a specific food.

FDA has fully evaluated and considered the arguments raised in both petitions. FDA recognizes that the 10 percent nutrient contribution requirement may have had the unintended effect of prohibiting health claims on certain foods that could be beneficial for consumers and help them to maintain a balanced and healthful diet. The agency is concerned, however, that eliminating the 10 percent nutrient contribution requirement will permit misleading health claims on foods with little or no nutritional value such as candies and soft drinks or will encourage overfortification of the food supply (e.g., vitamin or mineral addition to soft drinks). The appearance of health claims on such foods would be inconsistent with Congress's intent when it enacted the health claims provisions. As discussed in the 1993 health claims final rule, Congress enacted the health claims provisions of the 1990 amendments to not only protect consumers from health claims that are not scientifically valid but also to help consumers maintain healthy dietary practices by providing information that would be useful in constructing total daily diets that meet current dietary guidelines. Thus, an important part of the significance and benefit of health claims is that they appear on foods that are compatible with current dietary recommendations. (See H. Rept. 101–538, 101st Cong., 2d sess. pp. 9–10 (1990).)

During the development of the health claims final rule, FDA considered other alternatives that would ensure that health claims are not trivialized or rendered meaningless by appearing on foods of little or no nutritional value. For example, the agency considered prohibiting health claims on specific foods, such as confections, soda, and snack foods, based on the foods' categorization or characteristic use. However, as fully discussed in the 1993 health claims final rule (58 FR 2478 at 2521), the agency was not persuaded that such action was in keeping with the intent of the statute. The agency concluded that Congress did not intend that specific foods that could be in general use be prohibited from bearing a health claim. Thus, the agency concluded that a prohibition on health claims for specific categories of foods was not a viable option.

However, given the requirement in section 403(r)(3)(B)(iii) of the act that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet, FDA concluded (as discussed in the 1993 health claims final rule (58 FR 2478 at 2521–2522)) that it is appropriate to provide a basis for health claims that takes into account the nutritional contribution of the food beyond its role as a source of calories. The agency noted that ''Congress intended that FDA establish provisions of health claims regulations by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines'' (Id. at 2521). Without such provisions, foods that are not compatible with dietary guidelines could bear health claims. In addition to being inconsistent with Congress's intent when it established the health claim provisions, and section 403(r) of the act, claims intended to promote the consumption of a food that is incompatible with dietary guidelines would be misleading to consumers and, therefore, would be in violation of section 403(a) (id.). Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet, when, in fact, such foods are inconsistent with dietary guidelines. Further, such claims could be damaging if consumers are encouraged to replace wholesome and nutritious foods that are recommended in dietary guidelines with these foods.

Thus, the agency concluded then, and reiterates now, that the 10 percent nutrient contribution requirement is a necessary component of the health claims provisions to ensure that such claims appear on foods that make a nutritional contribution to the diet and are consistent with dietary guidelines. If the agency were to revoke this requirement, it would have to establish

an alternative mechanism to ensure that health claims are not made on inappropriate foods. The NFPA petition did not suggest any alternatives to the 10 percent nutrient contribution requirement to preclude misleading health claims on inappropriate foods.

The agency also tentatively concludes that the alternatives suggested in the ABA petition would not ensure that health claims were made only on foods that are consistent with dietary guidelines. Relying on either of the two alternatives suggested in the ABA petition would not adequately assist consumers in placing foods that bear health claims in their proper dietary context.

The ABA's suggestion that the nutrients required to be present at 10 percent be expanded to include thiamin, niacin, or carbohydrates would not encourage consumers to increase their intake of vitamins and minerals that have been identified as those of continuing public health significance. Public health concerns for deficient intakes of thiamin, niacin, or carbohydrates have lessened considerably in the last 20 years, whereas the inadequate intakes of vitamin A, vitamin C, calcium, and iron remain a public health concern especially because of the possible association between several of these nutrients and the risk of chronic disease. Furthermore, expanding the list of nutrients required to be at 10 percent to include thiamin, niacin, or carbohydrates would permit only certain foods to bear health claims, such as enriched cereal grain products. Certain fruit and vegetable products that are promoted in dietary guidelines but that are currently prohibited from bearing health claims would still not be able to bear a health claim. Consequently, the agency tentatively concludes that expanding the list of nutrients would not sufficiently address the concern that the current regulation precludes certain foods that contribute to a healthful diet, and whose consumption is encouraged by the dietary guidelines, from bearing health claims.

Likewise, permitting the 10 percent nutrient contribution requirement to be based on the daily consumption of a food group would not enhance the likelihood of consumers achieving dietary goals. In fact, such a requirement would be contrary to dietary goals because it would reduce the likelihood that a consumer would reach 100 percent of the DV if daily consumption of an entire food group only supplies 10 percent of one of the listed nutrients. One reason for requiring that a serving of the food provide 10 percent of one or more of the listed nutrients is to assist the consumer in achieving daily intakes recommended in current dietary guidelines. Permitting a food that does not meet the 10 percent nutrient requirement to bear a claim on the basis that the total daily consumption of foods from that category would provide 10 percent of the nutrient would be inconsistent with one of the basic principles of the requirement. Accordingly, the agency has not been persuaded by the arguments raised in the petitions to propose to eliminate the 10 percent nutrient contribution requirement, to expand the list of nutrients that will qualify a food to bear a health claim, or to allow the 10 percent nutrient requirement to apply to a daily consumption of grain products rather than to the nutrient profile of a specific food.

Regarding the request that FDA permit fortification to meet the 10 percent nutrient contribution requirement, the agency is concerned that fortification of foods solely to bear a health claim could result in deceptive or misleading labeling and, thereby, be in violation of section 403(a) of the act. As fully addressed in the 1993 health claims final rule (58 FR 2478 at 2522), fortification of a food of little or no nutritional value for the purpose of bearing a health claim has the great potential of misleading and confusing consumers if foods like confections, soda, and sweet desserts are fortified to qualify for a health claim when, at the same time, dietary guidance as contained in the Food Guide Pyramid, for example, states that ''[T]hese foods provide calories and little else nutritionally. Most people should use them sparingly'' (Ref. 3). Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines. Consequently, FDA has not been persuaded that foods should be permitted to be fortified to qualify to bear a health claim. Accordingly, FDA is denying NFPA's request to permit fortification to specifically qualify a food to bear a health claim.

The agency notes, as discussed in the 1993 health claims technical amendments (58 FR 44036 at 44037), that some foods either have been traditionally formulated in accordance with the fortification policy or to meet standards of identity that include fortification and, in that form, contain 10 percent or more of one of the six nutrients listed. In such cases, the agency notes that the food would not be precluded by § 101.14(e)(6) from being fortified to qualify for a health claim.

Although the agency has not been persuaded that elimination of the 10 percent nutrient contribution requirement is in order, or that it should permit fortification so that a food could qualify to bear a health claim, the agency has been persuaded by the arguments raised in the petitions that it should act to modify the 10 percent nutrient contribution requirement. As stated above, the agency acknowledges that the 10 percent nutrient contribution requirement has had the unintended effect of precluding some foods that contribute to a healthful diet, and whose consumption is encouraged by the dietary guidelines, from bearing health claims. As discussed above, the agency's primary goals in establishing the 10 percent nutrient contribution requirement were to preclude foods of little or no nutritional value from bearing health claims and, at the same time, to enhance the likelihood of consumers constructing overall daily diets that conform to current dietary guidelines.

FDA recognizes that precluding certain fruits, vegetables, and grain products from bearing health claims because of the 10 percent nutrient contribution requirement is contrary to that goal. The agency agrees with the arguments raised in the petitions that certain fruits, vegetables, and grain products that otherwise meet the requirements of the specific health claim should be able to bear the claim even though they do not contain 10 percent of one of the six listed nutrients because these foods comprise a major part of a balanced and healthful diet, and because current dietary guidance promotes consumption of these foods. Moreover, diets high in fruits, vegetables, and grain products have been associated with various specific health benefits, including lower occurrence of coronary heart disease and of some cancers (Refs. 4 and 5) and therefore, are exactly the types of foods that should be included in the diet to reduce the risk of specific diet-related diseases. Precluding such foods from bearing health claims could confuse consumers and undermine the utility of health claims.

Furthermore, the foods described in the petitions are not the types of foods FDA intended to preclude from bearing health claims when it established the 10 percent nutrient contribution requirement. In fact, these foods can contribute significantly to a balanced and healthful diet and to achieving compliance with dietary guidelines even though they do not meet the 10 percent nutrient contribution requirement. Consequently, the agency

tentatively concludes that fruit and vegetable products comprised solely of fruits and vegetables, enriched grain products that conform to a standard of identity, and bread that conforms to the standard of identity for enriched bread except that it contains whole wheat or other grain products not permitted under that standard, that do not meet the 10 percent nutrient contribution requirement but that meet all other aspects of the health claim should be permitted to bear a health claim. Accordingly, the agency is proposing to amend § 101.14(e)(6) to exempt these products from the 10 percent nutrient contribution requirement.

The agency is proposing to limit the exemption for fruit and vegetable products to those products comprised solely of fruits and vegetables because it is concerned that permitting health claims on fruit and vegetable products that do not contain 10 percent of one of the six listed nutrients, but that contain ingredients that may raise the level of certain other nutrients, such as fat, cholesterol, and sodium, would be inconsistent with the purpose of the health claim and incompatible with current dietary guidelines. While the agency recognizes that fruit and vegetable products with added syrups, sauces, and other ingredients that have increased levels of fat, cholesterol, or sodium have an appropriate place in the diet, the agency tentatively concludes that to exempt these products from the 10 percent nutrient contribution requirement would be to promote the consumption of foods that do not fall within the recommendations in dietary guidelines. Accordingly, the agency is not prepared to extend the exemption to these products. However, FDA requests comment on whether the exemption proposed in this document should be extended to include fruit and vegetable products with added oils, sodium, sauces, syrups, or other ingredients.

The agency also requests comment on whether other foods, for example, other types of grain products such as breakfast cereals, should be exempt from the 10 percent nutrient contribution requirement. The agency advises that comments submitted in support of extending this exemption to other foods should provide valid data and sound justification for exempting such foods from the 10 percent nutrient contribution requirement. If the comments persuade the agency that such foods are being unfairly precluded from bearing health claims, and that the foods are consistent with the intent of the health claims, the agency will consider including such foods in the exemption provided in any final regulation based on this proposal.

C. Abbreviated Health Claims

Current § 101.14(d)(2)(iv) mandates that all information required to be included in the claim appear in one place without other intervening material. The current rule, however, does permit a reference statement ''See———— for information about the relationship between———— and————,'' with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., ''See attached pamphlet for information about calcium and osteoporosis'') with the complete health claim appearing elsewhere on the other labeling. The current rule also permits the use of graphic material, such as a symbol that constitutes an expressed or implied health claim, to be used on the label or labeling of the product provided that it is accompanied by the complete claim, an abbreviated claim, or a referral statement (§ 101.14(d)(2)(iv)).

In the preamble to its 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). The agency was concerned that an abbreviated claim did not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet. The agency was concerned that such confusion is possible ''whenever the full health claim information appears in a location different from that of the reference statement and is especially likely to occur when a multiplicity of labeling is associated with a product'' (Id.). The agency then described the situation where the grocer displays an abbreviated claim on a display (labeling) near the product but only puts the full claim on a billboard in a far corner of the store (labeling) (id.).

In its petition, NFPA requested that the agency reconsider this position and permit greater latitude in constructing and presenting health claims. More specifically, the petition requested that FDA permit abbreviated health claims that are accompanied by a referral statement directing the consumer to the label panel where the complete health claim appears.

The agency has no desire for its regulations to unnecessarily stand in the way of the use of health claims and the presentation of the important information contained therein. While health claims are currently being used on the label and in labeling, the agency would like to see them used more extensively. Consequently, the agency agreed to initiate rulemaking in this area. The agency stated, however, that it must have assurance that the claims will be presented in a scientifically valid, truthful, and nonmisleading manner.

FDA notes that in this document the agency is proposing to provide the basis for shorter health claims by making optional some of the elements that it has required to be included in claims. If those changes are finalized, many of the complete claims will be brief enough to permit their use on the principal display panel. For example, a claim for sodium and hypertension could be made in 12 words: ''Diets low in sodium may reduce the risk of high blood pressure.'' Most other claims would be of a similar length. The agency believes that these shortened claims will, for the most part make this issue moot. Nevertheless, the agency recognized that some claims may still remain somewhat complex.

In those cases where the complete health claim remains long and somewhat complex, the agency recognizes that there may be a need to permit a shortened version of the claim on the principal display panel. Although the entire health claim contains important information necessary for consumers to fully understand the subject substance-disease relationship, the agency recognizes that a short message that captures the consumer's attention will facilitate use of the claim. As a result, the communication of formation will assist consumers in achieving healthful dietary practices.

The agency tentatively concludes that the use of an abbreviated health claim on the principal display panel is consistent with the act. The full health claim includes information required under section 403(a) and 403(r)(3)(B)(iii) of the act. Section 403(r)(3)(B)(iii) requires that the complete health claim ''enable[] the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.'' Section 403(a) of the act requires only that a claim not be false and misleading. FDA has long required that all information that is necessary to make the claim truthful and not misleading appear in one place, without any intervening material. (See, e.g., *United States* v. *An Article of Food * * * ''Manischewitz * * * Diet Thins*'', 377 F. Supp. 746 (E.D. New York 1974)). However, there is nothing in the act that would require that information required under section 403(r)(3)(B)(iii) appear as

part of the claim each time it is presented on the label.

Thus, an abbreviated health claim that is a scientifically valid representation of the relationship between a substance and a diet-related disease may be permissible under section 403(a) of the act if it is truthful and not misleading. If such an abbreviated claim includes a prominent and immediately adjacent reference to the full claim elsewhere on the label, the requirements of section 403(a) and (r)(3)(B)(iii) of the act would be fulfilled. Consequently, the agency is proposing to amend § 101.14(d)(2)(iv). In addition to permitting the current reference statement to the full claim (§ 101.14(d)(2)(iv)(A)), the agency is proposing to permit an abbreviated health claim to be used on the principal display panel of the label provided that it is accompanied by a reference statement to the complete health claim on the same label or in the same labeling (proposed § 101.14(d)(2)(iv)(B)).

It is vital to compliance with the act that the complete claim appear elsewhere on the same label or in the same labeling as the abbreviated claim. For example, as discussed below for the calcium and osteoporosis health claim, the agency is concerned that consumers might be less likely to read the full health claim if an abbreviated claim appears on the principal display panel of a label, and the full health claim appears in a separate brochure that accompanies the product.

The agency is also proposing to require that the reference statement be prominent and in immediate proximity to the abbreviated claim. The agency notes, of course, that if the proposed provision is adopted, an abbreviated claim could not be used unless the food meets the criteria necessary to make the complete health claim.

As stated above, in the section D.IV. of this document, the agency is proposing to amend the regulations in subpart E of part 101, where appropriate, to set forth the elements that are required to ensure that an abbreviated health claim complies with section 403(a) of the act. As stated above, provision for an abbreviated claim will not be needed for most of the nutrient-disease relationships about which FDA has authorized claims if the revisions proposed in this document are adopted. Consumers may benefit, however, from abbreviated claims for a few of the longer, more complicated claims, such as those for calcium/osteoporosis and folic acid/neural tube defects.

The agency strongly emphasizes that the diet-disease relationship may not be overstated. Even with a prominent referral to the full claim, the abbreviated claim must not overemphasize the importance of the substance in the diet-disease relationship or in the total daily diet. The concept of risk reduction must be accurately conveyed.

The agency notes that some of the diet-disease relationships may already be well-known by consumers. Therefore, nutrient content claims such as ''low sodium'' and ''reduced cholesterol'' on the principal display panel and elsewhere on the label may serve as a reminder of the diet-disease relationship and provide a way to market a product for its contribution to a healthy diet.

FDA encourages the use of all authorized claims by the food industry in order to educate consumers about the importance of a healthy diet. The agency believes that the proposed changes to § 101.14(d)(2)(iv) will result in increased use of the authorized health claims and, consequently, will fulfill the legislative intent to educate the public about diet-disease relationships.

D. Specific Requirements for Health Claims

To date, FDA has authorized eight health claims that are codified in the Code of Federal Regulations, Title 21, subpart E of part 101 (§§ 101.72 to 101.79). Among the actions requested by NFPA in its petition is one to ''* * * modify the regulations in subpart E of part 101 prescribing the content of authorized health claims so that they constitute 'safe harbors' rather than requirements for claims; * * *.'' To accomplish this request, NFPA requested that the health claims regulations be modified to permit simplified, nondeceptive claims that are likely to be more easily understood. NFPA contended that the specific health claims regulations contained in subpart E of part 101 include several provisions that prescribe the content and form of health claims to an extent that far exceeds that necessary to ensure that claims are truthful and not misleading. Mentioned as an example was that some regulations require claims to include references to specific nondietary factors even though, in NFPA's view, this information is unnecessary to ensure a claim is stated in a truthful, nonmisleading manner. Cited as illustrative of the nature of the problem was the model claim from the calcium/osteoporosis regulation (§ 101.72(e)) containing all required elements:

> Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Each of the other regulations authorizing claims in subpart E of part 101 was identified as requiring similar information.

NFPA requested that the regulations in subpart E of part 101 governing the specific information that must appear in a health claim, and the circumstances in which a claim could be used, be amended. Where, for example, § 101.14(d)(2)(i) requires that labeling statements about a health claim be based on, and consistent with, the conclusions set forth in the regulations in subpart E of part 101, NFPA recommended amending § 101.14(d)(2)(i), along with § 101.14(d)(1) and the rest of (d)(2), so that such statements are objective and either consistent with applicable guidelines set forth in subpart E of part 101, or a reasonable basis for the claim is otherwise substantiated. The petitioner contended that such changes would operate to allow truthful, nonmisleading health claims that either omit information currently required under the regulations (e.g., nondietary information) or that include other useful information not expressly authorized by the regulations.

Responding to NFPA in the May 11, 1995, letter, FDA acknowledged that, although use of health claims in food labeling has increased over the period of time that they have been in effect, the number of products bearing such claims is not as great as the agency had anticipated. Because of the importance of the information conveyed to consumers by health claims, the agency stated that it would review the authorizing regulations to determine whether they contain any unnecessary barriers to the use of the claims and, if so, take steps to remove those barriers. FDA stated that, as part of this assessment, it would conduct a review of what are referred to as ''required elements'' in each of the eight authorized health claims to determine whether any of them are unnecessary or can be made optional and initiate rulemaking to propose any changes identified in its internal review.

The eight authorized health claims in subpart E of part 101 are codified following the same format. Thus the ''required elements'' for each claim are contained in paragraph (c) of the respective regulation under the heading ''Requirements.'' For example, specific requirements that apply to the calcium/osteoporosis health claim are contained in § 101.72(c)(2)(i)(A) through (c)(2)(i)(E).

The agency has reviewed all of the required elements in the eight authorized claims codified in subpart E of part 101. This document presents the results of this review for the following seven claims: § 101.72 on calcium and osteoporosis; § 101.73 on dietary lipids and cancer; § 101.74 on sodium and hypertension; § 101.75 on dietary saturated fat and cholesterol and risk of coronary heart disease; § 101.76 on fiber-containing grain products, fruits, and vegetables and cancer; § 101.77 on fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease; and § 101.78 on fruits and vegetables and cancer. The health claim on folate and neural tube defects (§ 101.79) will be dealt with separately but in a manner consistent with the review of the other health claims.

Since the final rules on the seven claims addressed in this document were published on January 6, 1993 (58 FR 2537 to 2849), new data have become available allowing FDA to reconsider the need for some information that, at the time the specific health claim regulations were issued, was considered necessary to preclude a claim from being misleading. Most notable among these data are two documents, one a National Institutes of Health (NIH) consensus statement on optimal calcium intake (hereinafter referred to as the 1994 consensus statement) and the other an FDA report on consumer understanding of health claims (hereinafter referred to as the 1995 consumer report) (Refs. 6 and 7, respectively).

1. The Calcium/Osteoporosis Health Claim

The 1994 consensus statement is the result of the Consensus Development Conference on Optimal Calcium Intake convened by NIH on June 6 through 8, 1994, which brought together experts in public education and different biomedical sciences dealing with osteoporosis and bone and dental health. Directly relevant to the calcium/osteoporosis health claim, this conference addressed questions and provided recommendations on optimal calcium intake for various population segments, on important cofactors for achieving optimal intake, on the risks associated with increased intake, on the best ways to attain optimal intake, and on the public health strategies that are available or are needed to implement optimal calcium intake recommendations.

The 1995 consumer report is part of FDA's ongoing review of its regulations governing health claims. The report evaluated consumer understanding of four health claims (dietary lipids and cancer, fruits and vegetables and cancer, calcium and osteoporosis, and folate and neural tube defects) and consumer reaction to possible variations on the messages. The report describes the content, the manner of presentation, and the results of a consumer survey of knowledge about the four health claims mentioned above among consumer groups at eastern, central, and western locations in the United States.

For the calcium/osteoporosis health claim, the first required element is contained in § 101.72(c)(2)(i)(A) and provides that:

> The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed.

The effect of presenting the information required by this element is to convey the message that, for any individual, several factors define the disease risk.

The focus of the 1994 consensus statement is, as stated in its title, optimal calcium intake for promotion of public health. The first of several significant conclusions in the report is that a large percentage of Americans fail to meet currently recommended guidelines for optimal calcium intake. Because of the need to correct this public health shortfall and to improve bone health in the United States, thereby reducing the risk of osteoporosis, FDA tentatively concludes that a singular focus on achieving and maintaining adequate calcium intake as a required element in the calcium/osteoporosis health claim is important.

Accordingly, FDA is proposing to simplify § 101.72(c)(2)(i)(A) by limiting the requirement to a balanced statement that reflects the importance of the essential nutrient calcium over a lifetime in a healthful diet to reduce osteoporosis risk, but that does not imply that calcium is the only risk factor for the development of osteoporosis. To this end, proposed § 101.72(c)(2)(i)(A) states that the claim must make clear that adequate calcium intake as part of a healthful diet throughout life is essential to reduce the risk of osteoporosis.

FDA has included the reference to a ''healthful diet'' in proposed § 101.72(c)(2)(i)(A) for consistency with the general requirement in § 101.14(d)(2)(v) that ''the claim enable[ ] the public * * * to understand the relative significance of such information [in this case, the relationship between calcium and osteoporosis] in the context of a total daily diet.'' The effect of adequate calcium intake can only be realized if the calcium is a part of a healthy diet that provides all essential and other nutrients to optimize nutritional health status.

The proposed revision of § 101.72(c)(2)(i)(A) emphasizes the most important risk factor in the development of osteoporosis on the label of a food product, i.e., adequacy of dietary calcium intake. Nevertheless, the agency is concerned that such a claim could lead consumers to believe that adequacy of dietary calcium intake is the only risk factor for the disease. In the proposal to authorize the calcium/osteoporosis health claim, the following was stated:

> Calcium intake is not the only recognized risk factor in the development of osteoporosis. Other factors include a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices, such as smoking and excess alcohol consumption.

(56 FR 60689 at 60698, November 27, 1991). Based on that information in part, § 101.72(c)(2)(i)(A) requires a listing of several specific risk factors, in addition to dietary calcium intake, in the calcium/osteoporosis health claim.

As stated above, however, FDA acknowledges that the number of food products bearing health claims is not as great as the agency had anticipated. FDA is concerned that manufacturers have been disinclined to use lengthy health claims on food labels, and that too many words will detract from the central consumer message of the claim. As a result, FDA is concerned that health claims like the calcium/osteoporosis claim will continue to be infrequently used, and that the benefits of communicating information on diet-disease relationships through such claims will not be realized.

Because of these concerns, the agency has reevaluated the requirement in § 101.72(c)(2)(i)(A) that a calcium/osteoporosis health claim ''* * * list[ ] specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stat[e] that an adequate level of exercise * * * [is] also needed.'' Given the consensus statement's central focus on optimal calcium intake and the agency's desire to make health claims as useful and useable as possible, FDA is proposing to replace the requirement in § 101.72(c)(2)(i)(A) that specific risk factors and the need for an adequate level of exercise be stated in any claim with the more simple requirement that the claim not imply that adequate dietary calcium intake is the only recognized risk factor for a reduced risk

of osteoporosis. This revision will ensure that the scientific validity of claims about osteoporosis is preserved by recognizing the multifactorial nature of this disease without adding words to the claim.

In concert with the proposed change in § 101.72(c)(2), the agency is proposing to redesignate § 101.72(d)(2) as paragraph (d)(5) and to add a new paragraph (d)(2) that provides for the provision of the following information from current § 101.72(c)(2)(i)(A) as optional information:

> The claim may list specific risk factors for osteoporosis, identifying them among the multifactorial risks for the disease. Such factors include a person's sex, age, and race. The claim may state that an adequate amount of exercise is also needed to reduce risk for the disease.

The 1995 consumer report identified the calcium/osteoporosis model health claim as the one most actively disliked (Ref. 7). This dislike most likely arises primarily from a misunderstanding one of the concepts required in § 101.72(c)(2)(i)(B), specific identification of the populations at particular risk for the disease. The current regulation states:

> The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term ''Caucasian'') women and Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase ''during teen or early adult years'' may be used). The claim may also identify menopausal (or the term ''middle-aged'') women, persons with a family history of the disease, and elderly (or ''older'') men and women as being at risk.

The 1995 consumer report states that minority women were unanimous in objecting to the inference that black American women do not need calcium. Accordingly, minority participants questioned the accuracy of the information. All of the survey participants recognized that calcium is essential for everyone. Although there was some recognition based on prior knowledge that younger women need to be concerned about osteoporosis, no participant thought the model claim communicated that concept very well. For these and other reasons, older women tended to dismiss the model claim as incorrect.

The agency did not intend that the calcium/osteoporosis health claim imply that calcium is not needed by any individual or specific population. Given that calcium is essential for every person, the agency attempted to craft requirements for presenting this disease claim in a truthful, nonmisleading, and scientifically valid manner. In reviewing the scientific data supporting the claim, including the incidence of low-trauma bone fracture in the elderly, FDA stated in the preambles to the calcium/osteoporosis proposed and final rules (56 FR 60689 and 58 FR 2665, respectively) that those individuals in the general population at greatest risk of developing osteoporosis, and for whom the health claim would have greatest benefit, include Caucasian and possibly Asian women and adolescent girls and young adult women between 11 and 35 years of age. For this and other reasons, a requirement for identifying these high risk groups was included in § 101.72(c)(2)(i)(B). In identifying those at highest risk, there was no intent by the agency to imply that other consumers are risk free.

The 1994 consensus statement is silent in ascribing relative risk for osteoporosis on the basis of race or ethnicity of population groups. For adolescents and young adults of both sexes, 11 through 24 years of age, the optimal calcium requirement is given as a range of 1,200 to 1,500 milligrams (mg) of calcium daily. The report says the following about a subset of this population, 12 to 19 year old females:

> Importantly, population surveys of girls and young women 12–19 years of age show their average calcium intake to be less than 900 mg/day, which is well below the calcium intake threshold. The consequences of low calcium intake during this crucial period of rapid skeletal accrual raise concerns that achievement of optimal peak adult peak bone mass may be seriously compromised. Special education and public measures aimed at improving dietary calcium intake in this age group are essential.

(Ref. 6.)

FDA tentatively concludes that greater use in food labeling of the calcium/osteoporosis health claim, articulated in a manner that will be accepted and followed by consumers, can help support significant strides in improving calcium intake in all segments of the U.S. population. Accordingly, the agency is proposing to revise § 101.72(c)(2)(i)(B) in several ways.

First, it is proposing to revise § 101.72(c)(2)(i)(B) by removing the requirement to identify by race those populations at particular risk for the development of osteoporosis. In neither the statement cited above nor elsewhere in the 1994 consensus statement is any racial or ethnic segment among girls and young women 12 to 19 years of age identified as being more at risk for the consequences of a less than optimal calcium intake. The 1994 NIH consensus statement found that the recommendation for optimal nutrient requirements for any particular age/sex population segment to forestall the impact of a degenerative disease applies to all members of that segment, although not necessarily to the same degree for everyone. Thus, the agency is proposing not to require mention of race or ethnicity as a required element but to permit such information as an option since it is useful and important to those to whom it applies.

Nevertheless, retention of teen and young adult women, irrespective of race or ethnicity, as the focus of the claim is important because, as stated succinctly in the 1994 consensus statement:

> Two important factors that influence the occurrence of osteoporosis are optimal bone mass attained in the first two or three decades of life and the rate at which bone is lost in later years.

Failure to attain optimal bone mass during the bone-forming years of adolescence and early adulthood is a loss that cannot be recovered during middle age or later in life (Ref. 6). Once peak adult bone mass is reached at about age 25, bone turnover is stable in men and women such that bone formation and bone resorption (breakdown) are balanced. In women, resorption rates increase, and bone mass declines, beginning with the fall in estrogen production that is associated with the onset of menopause. Unlike hormone replacement therapy, supplemental calcium during this initial phase will not slow the decline in bone mass attributable to estrogen deficiency. The effects of calcium in reducing the rate of bone loss can be shown more clearly in postmenopausal women after the period when the effects of estrogen deficiency are no longer dominant (i.e., about 10 years after menopause).

Osteoporosis affects more than 25 million people in the United States and is the major underlying cause of bone fractures in postmenopausal women and the elderly (Ref. 6). Given this tremendous cost to public health, it is essential that the health claim on calcium and osteoporosis inform consumers, particularly those at great risk for the disease, of the importance of adequate calcium intake throughout life for attaining peak adult bone mass and for reducing the rate of bone resorption or loss, two processes that occur at different periods over a lifetime.

Thus, FDA is proposing to retain the requirement in § 101.72(c)(2)(i)(B) that the claim not suggest that the risk of osteoporosis applies equally to the general U.S. population. However, it is proposing to remove the required

reference to any racial or ethnic group in identifying the at-risk population. The agency is proposing to identify this population in the following way:

> * * * The claim shall identify the population at particular risk for the development of osteoporosis as women in their bone forming years from approximately 11 to 35 years of age. An optional statement that further characterizes this and other populations at risk for developing osteoporosis may be made in accordance with paragraph (d)(3) of this section.

FDA is proposing to permit identification of Caucasian women and Asian women as among those at particular risk for the disease as optional information, along with other information from § 101.72(c)(2)(i)(B), in new § 101.72(d)(3). While the 1995 consumer report (Ref. 7) found evidence that some consumers could be misled by references in the calcium/osteoporosis health claim to Caucasian and Asian women, FDA tentatively concludes that, if properly qualified, this information could be helpful in informing such women who may be unaware of their risk of developing this disease. By providing for this information as an optional element in § 101.72(d), the agency is attempting to encourage manufacturers to use this information in formats where the message can be phrased in enough detail to clarify its meaning. For example, ''while all women may be at risk of osteoporosis, Caucasian and Asian women are particularly at risk,'' may be understood and not rejected by consumers. While this statement provides more detail than seems to be necessary in the basic health claim, this information could be useful in a longer discussion of calcium and osteoporosis, for example in a paragraph format on a large label or in a pamphlet. The agency requests comment, and is particularly interested in data, on whether its tentative view that consumer understanding would be helped is correct.

Section 101.72(c)(2)(i)(C) established a requirement for identifying the mechanism whereby adequate dietary calcium over a lifetime should reduce the risk of osteoporosis:

> The claim states that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase ''build and maintain good bone health'' may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss.

The agency concluded in developing this requirement that it is important for consumers to have a basic understanding of the biological and physiological mechanisms by which adequate dietary intake of calcium achieves a reduced risk of osteoporosis. However, information developed since the regulation was published indicates that a health claim may not be the best way to provide this information. The 1995 consumer survey (Ref. 7) found that, because participants had learned elsewhere that calcium intake is related to general bone health, they thought the food label was not the right means for conveying this information. In addition, this awareness by consumers that calcium's ability to ''build and maintain good bone health'' is the mechanism whereby risk of osteoporosis is reduced, raises a question as to whether there is a need to state that fact in a health claim. In the interest of streamlining the claim, therefore, FDA is proposing to make the statement of the mechanism by which calcium intake affects the risk of osteoporosis optional information. The agency is proposing to move § 101.72(c)(2)(i)(C) to § 101.72(d)(4), changing only the word ''shall'' to ''may''.

Section 101.72(c)(2)(i)(D) requires that:

> The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life;

This paragraph is consistent with requirements in regulations for all other authorized claims that no attribution to degree of risk reduction for the respective disease or health-related condition be made in reference to the nutrient or substance that is the subject of the claim (see, for example: §§ 101.73(c)(2)(i)(E), 101.74(c)(2)(i)(D), 101.75(c)(2)(i)(D), 101.76(c)(2)(i)(E), 101.77(c)(2)(i)(G), 101.78(c)(2)(i)(E), and 101.79(c)(2)(i)(F).

Unlike these other regulations, § 101.72 does not contain an express requirement that the claim state that adequate calcium intake throughout life ''may'' or ''might'' reduce the risk of osteoporosis (see, for example, paragraphs (c)(2)(i)(A) in §§ 101.73 through 101.79). However, it is clear that FDA also intended that this requirement apply to the calcium/osteoporosis health claim. This intention may be inferred from the two model health claims that use the term ''may'' in relating calcium intake with a reduction in risk of osteoporosis. Accordingly, the agency is proposing to revise § 101.72(c)(2)(i)(D) and redesignate it as § 101.72(c)(2)(i)(C) to read as follows:

> The claim does not attribute any degree to which maintaining adequate calcium intake throughout life may reduce the risk of osteoporosis;

This proposed revision retains the prohibition against attributing the degree to which adequate calcium intake is associated with a reduced risk for osteoporosis while introducing the concept that, because of the multifactorial nature of the disease, maintenance of an adequate calcium intake throughout life may reduce risk of developing the disease.

Section 101.72(c)(2)(i)(E) contains the conditional requirement that a calcium/osteoporosis health claim include a statement that reflects the limit on the benefit derived from dietary calcium intake as follows:

> The claim states that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health. This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed as defined in § 101.12(b) or per total daily recommended supplement intake.

Most conventional foods and many calcium-fortified foods do not exceed the threshold of 40 percent of the DV for calcium for adults and children 4 or more years of age and, therefore, do not trigger the required use of the statement in § 101.72(c)(2)(i)(E). Dietary supplements containing calcium, particularly single nutrient supplements containing 500 or 600 mg of calcium per tablet, exceed the threshold and are therefore required to bear the statement as part of a health claim. The Dietary Supplement Health and Education Act of 1994 (the DSHEA) (Pub. L. 103–417) was enacted on October 25, 1994, and amends the act (Ref. 8). Among the findings of Congress for this new law regarding the benefits of dietary supplements to health promotion and disease prevention is one that identifies a link between ingestion of certain nutrients or dietary supplements and reduced risk for several chronic diseases including osteoporosis. Another finding states that the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.

Among the issues addressed in the 1994 consensus statement is the question of the ways by which optimal calcium intake may be attained. The

document draws the following conclusion:

> The preferred source of calcium is through calcium-rich foods such as dairy products. Calcium-fortified foods and calcium supplements are other means by which optimal calcium intake can be reached in those who cannot meet this need by ingesting conventional foods.

The agency has taken into consideration the expressed intent of the DSHEA and this finding from the 1994 consensus statement and tentatively concludes that revision of § 101.72(c)(2)(i)(E) is in order. The agency is proposing to raise the threshold for the required statement from 400 to 1,500 mg of calcium, along with other changes.

With regard to adverse effects and the risks associated with increased levels of calcium intake, the 1994 consensus statement states the following:

> Even at intake levels of less than 4 g/day, certain otherwise healthy persons may be more susceptible to developing hypercalcemia or hypercalciuria. Likewise, subjects with mild or subclinical illnesses marked by dysregulation of 1,25-dihydroxyvitamin D synthesis (e.g., primary hyperparathyroidism, sarcoidosis) may be at increased risk from higher calcium intakes. Nevertheless, in intervention studies (albeit of relatively short duration--less than 4 years), no adverse effects of moderate supplementation up to 1500 mg/day have been reported.

(Ref. 6.)

The same document concludes that daily calcium intake, up to a total of 2,000 mg, appears to be safe in most individuals (Ref. 6). For major segments of the U.S. population the 1994 consensus statement identifies an optimal calcium requirement of either 1,500 mg or a range of 1,200 to 1,500 mg of calcium per day. These population groups include adolescents and young adults 11 to 24 years of age, pregnant and lactating women, women over 50 (postmenopausal) who are not on estrogens, and men over 65 years of age (Ref. 6). Therefore, the agency tentatively finds that a level of 1,500 mg of calcium as the proposed threshold for the statement in § 101.72(c)(2)(i)(E) is not only consistent with current recommendations for dietary calcium intake but is also well within a range that is not known to cause adverse effects.

The agency is consequently proposing to require that the statement of limited benefit appear only on foods that provide more than 1,500 mg of calcium per day. FDA has expressed this proposed threshold level as a percentage of the Daily Values (DV's) for adults and children 4 or more years of age and for pregnant or lactating women. The agency notes that the calcium DV's for adults and children 4 or more years of age and for pregnant or lactating women have not changed and are 1,000 and 1,300 mg, respectively. (See § 101.9(c)(8)(iv) and 58 FR 2206 at 2213.) The agency intends to redesignate this requirement as § 101.72(c)(2)(i)(D).

A common form of a calcium dietary supplement in the marketplace is as a tablet containing either 500 or 600 mg of calcium as the sole nutrient with directions for use in labeling that recommend an intake of one or two tablets per day. A health claim in the labeling of such a product would not require the additional statement in proposed § 101.72(c)(2)(i)(D). FDA tentatively concludes that this proposed change is consistent with the recommendation from the 1994 consensus statement on dietary sources for this nutrient.

For consistency with the proposed revisions in § 101.72(c) and (d), FDA has revised the model health claims in proposed § 101.72(e). FDA has used the phrase ''Especially for teen and young adult women'' in example 1, which sets out how a claim that conforms with § 101.72(c) might look to reflect the effects on the risk of developing osteoporosis that may be realized by this population segment without implying that adequate calcium intake is without benefit for others.

The agency solicits comment on the proposed revisions to the calcium/osteoporosis health claim and is particularly interested in data on consumer understanding of this claim, and how such understanding can be improved.

2. Other Health Claims

A common requirement in the authorized claims for dietary fat and cancer (§ 101.73); sodium and hypertension (§ 101.74); dietary saturated fat and cholesterol and risk of coronary heart disease (§ 101.75); fiber-containing grain products, fruits, and vegetables and cancer (§ 101.76); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (§ 101.77); and fruits and vegetables and cancer (§ 101.78) is a statement that development of the particular disease depends on many factors.

It is well documented over the past 10 years that consumers are generally aware that development of major chronic diseases, such as cancer and coronary heart disease, is dependent on a number of different factors such as smoking, excess body weight, family history of the disease, exposure to environmental chemicals, and dietary and other factors (Refs. 9 and 10). Additionally, the requirement that authorized claims use the term ''may'' or ''might'' to relate the ability of the substance that is the subject of the claim to reduce the risk of the corresponding disease or health-related condition is an indication to consumers of the multifactorial nature of the disease or health-related condition. In responding to comments on the scientific standard for health claims as to whether or not a claim based on preliminary scientific data would be consistent with that standard, the agency said:

> * * * Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term ''may'' with respect to the potential to reduce the risk of disease. However, use of this term would not be appropriate for health claims on food labeling where significant scientific agreement does not exist that there is a high probability that a reduction in disease risk will occur.

(58 FR 2478 at 2505.)

Given these facts, as part of its review of required elements for all health claims the agency has reconsidered the need to remind consumers of the multifactorial nature of hypertension, heart disease, and cancer. Based on its review, FDA tentatively concludes that the statement of that fact in each claim can be made optional. In place of the requirement for stating the multifactorial nature of the disease, the agency proposes to substitute a requirement that the claim not imply that the substance that is the subject of the health claim is the only recognized risk factor for the corresponding disease or health-related condition. Thus, the agency tentatively concludes that the concept of the multifactorial nature of the disease or health-related condition for each health claim will be preserved without adding additional words to the claim. The agency requests comment on whether consumers will be misled to believe reduction of risk will be achieved if the multifactorial nature of

the disease or health-related condition is not stated in the claim.

Accordingly, the agency is proposing to revise §§ 101.73(c)(2)(i)(F), 101.74(c)(2)(i)(E), 101.75(c)(2)(i)(E), 101.76(c)(2)(i)(D), 101.77(c)(2)(i)(F), and 101.78(c)(2)(i)(I) in similar fashion to ensure that the health claim not imply that there is only one recognized risk factor for the development of the corresponding disease or health-related condition. The agency is also proposing to revise §§ 101.73(d)(1), 101.74(d)(1), 101.75(d)(1), 101.76(d)(2), 101.77(d)(1), and 101.78(d)(2) to state that development of the disease in question depends on many factors and to list the relevant factors for each disease. For consistency, the agency is also proposing to revise the model claims to reflect the proposed revisions to §§ 101.73, 101.74, 101.75, 101.76, 101.77, and 101.78.

In addition, the agency is proposing to correct § 101.77(e) by adding the phrase ''and the risk of coronary heart disease'' which was inadvertently omitted in the final rule.

The health claim for fruits and vegetables and cancer (§ 101.78) contains one additional element that FDA tentatively concludes could be optional instead of a mandatory part of the claim. In § 101.78(c)(2)(i)(D) the regulation states:

> The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under § 101.54: dietary fiber, vitamin A, or vitamin C.

This required statement is very similar to the one required by § 101.78(c)(2)(i)(C):

> The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber.

The agency believes that the statement required by § 101.78(c)(2)(i)(C) is necessary to describe the relationship between the food and the disease. In the 1993 health claims final rule, FDA stated that by requiring that all characterizing nutrients be identified as characteristic of dietary patterns rich in fruits and vegetables without specifically attributing reduced cancer risk to a single nutrient, the claim is consistent with current scientific knowledge. However, the requirement in § 101.78(c)(2)(i)(D) identifies for the consumer which of the characterizing nutrients is contributed by the labeled food. FDA tentatively concludes that this information need not be a required element of the claim because it is available as part of the nutrition label.

Therefore, the agency has tentatively concluded that the information in § 101.78(c)(2)(i)(D) can be made optional. Accordingly, the agency is proposing to remove § 101.78(c)(2)(i)(D); redesignate § 101.78(d)(3) through (d)(5) as § 101.78(d)(4) through (d)(6), and add new § 101.78(d)(3) which reads:

> The claim may characterize fruits and vegetables that meet the requirements described in paragraph (c)(2)(ii) of this section as foods that are low in fat and that contain (or are a good source of) one or more of vitamin A, vitamin C, or dietary fiber.

FDA is also proposing to revise the model health claims in § 101.78(e) to reflect these changes.

3. Abbreviated Health Claims

In addition to eliminating some of the requirements for a full health claim, as stated above, NFPA requested that FDA permit the use of abbreviated health claims in labeling, such as on the principal display panel. FDA has reviewed the health claims as it is proposing to revise them to determine whether the required elements can be reorganized in accordance with proposed § 101.14(d)(2)(iv) to facilitate their use on the food label.

With the revisions to §§ 101.73, 101.74, 101.75, 101.76, 101.77, and 101.78 proposed in this document, the agency tentatively finds that all of the required elements for each of the claims are required under section 403(a) of the act to ensure that the claims are truthful and not misleading as well as under section 403(r) to ensure that they are scientifically valid. Accordingly, the agency tentatively concludes that there is no basis upon which it can propose to permit the splitting of these required elements between the principal display panel and another part of the food label.

Using the health claim for dietary fat and cancer as an example, the agency is proposing to remove the requirement that the claim state that cancer is a multifactorial disease. The remaining specific requirements in § 101.73(c)(2)(i)(A) through (c)(2)(i)(E) are necessary so that claims on the relationship between dietary fat and cancer are truthful, not misleading, and scientifically valid. A claim consistent with these requirements can be expressed in 11 or fewer words (e.g., ''A low fat diet may reduce the risk of some cancers''). These requirements also ensure that consumers will be able to understand the relative significance of the information presented in the claim in the context of a total daily diet. Accordingly, the agency tentatively finds that there is no need to divide the required elements of § 101.73 into those that must be included whenever the claim is presented and those that need only be included as part of the full claim. Based on the same reasoning, FDA has reached the same judgment about the elements of the claims authorized by §§ 101.74 through 101.78.

The agency tentatively concludes, however, that such a split is appropriate among the required elements of health claims on calcium and osteoporosis (§ 101.72). The various proposed revisions for the specific requirements in § 101.72(c)(2)(i) would produce a claim that is shorter than is provided for in the current regulation. Nonetheless, even with the proposed revisions, the length of the claim that would be required under § 101.72 is such that, to facilitate use of the claim, FDA is proposing to distinguish between those elements necessary to ensure that the claim is truthful and not misleading, and those elements that are necessary to understand the significance of the claim in the context of the total daily diet.

Section 101.72(c)(2)(i)(A), which the agency is proposing to revise, sets forth the most important requirement. It establishes the essence of the calcium/osteoporosis claim in that it requires clarity in a statement that associates adequacy of dietary calcium intake over a lifetime with a reduced risk of osteoporosis, a degenerative disease that affects more than 25 million Americans, particularly postmenopausal women and the elderly, and that is manifested by an incidence of 1.5 million bone fractures annually (Ref. 6). This provision sets out information that is fundamental if a claim associating calcium and osteoporosis is to be truthful and not misleading.

Section 101.72(c)(2)(i)(C), which requires that the claim not attribute any particular degree of risk reduction to adequate calcium intake is also necessary to ensure that claims are truthful, not misleading, and scientifically valid. Compliance with this requirement, however, does not add any words to the claim.

For the remaining requirements, § 101.72(c)(2)(i)(B) prohibits the implication that risk for the disease applies equally across the U.S. population. Instead, it requires identification of that segment of the population that is most at risk for developing the disease later in life, women in their bone forming years. The agency requires this information in response to section 403(r)(3)(b)(iii) of the act, which as stated above, requires that the claim accurately represent the relationship between calcium and osteoporosis in a manner that is comprehensible to the public. It is also under section 403(r)(3)(b)(iii) of the act

that FDA is requiring in § 101.72(c)(2)(i)(D) that the claim disclose that further benefit does not derive from a daily dietary intake of calcium that exceeds 2,000 mg.

Given these bases for the calcium/osteoporosis claim, an abbreviated claim consistent with the principles proposed earlier in this document may be developed that sets out the information required under § 101.72(c)(2)(i)(A) and (c)(2)(i)(C). To reflect this fact, the agency is proposing to renumber current § 101.72(c)(2)(ii), which deals with the nature of a food bearing a calcium/osteoporosis health claim, as § 101.72(c)(2)(iii), and it is proposing a new § 101.72(c)(2)(ii) that describes how the health claim is to be presented on the label or in labeling. This proposed new paragraph states that all of the elements listed in § 101.72(c)(2)(i) must be included in one presentation of the claim on the label or labeling. However, it also provides that a short, simple statement of the claim that includes the elements in § 101.72(c)(2)(i)(A) and (c)(2)(i)(C), and thus that is truthful, not misleading, and scientifically valid, may be used on the principal display panel as long as the full claim appears on the label or in the labeling, and, there is a referral statement to the full claim in immediate proximity to the abbreviated statement.

The referral statement that FDA is proposing accompany the abbreviated claim is consistent with that provided for in the general requirements for nutrient content claims (§ 101.13) and health claims (§ 101.14(d)(2)(iv)). Because this referral statement is short, it is also consistent with the use of an abbreviated claim.

In the 1993 health claims final rule, the agency stated that it did not believe that it is appropriate to use abbreviated health claims as referral statements (58 FR 2478 at 2512). The agency was concerned that an abbreviated claim did not include facts that are material in light of the representation that is made and that are necessary to understand the claim in the context of the daily diet. The agency was concerned that such confusion is possible whenever the full health claim information is in a location different from that of the reference statement, and that such confusion is especially likely to occur when a multiplicity of labeling is associated with a product. If these concerns can be addressed, however, the use of an abbreviated claim on the principal display panel would facilitate use of the claim and, as a result, the communication of information that will assist consumers in achieving healthful dietary practices.

The agency has tentatively concluded that this proposed rule addresses these concerns. It is providing for an abbreviated statement that reflects the facts that are material under section 201(n) of the act (21 U.S.C. 321(n)) and that are necessary to ensure that the claim is scientifically valid. It is also providing for an accompanying referral statement to additional information that is necessary for a full understanding of the claim. The agency is concerned, however, about the possibility that consumers may not read the complete claim, and thus that they will not have all the facts necessary to fully understand the significance of the claim being made and to comprehend the claim in the context of the daily diet. For this reason, the agency is asking for data to demonstrate that permitting an abbreviated claim in the manner that FDA has proposed will not significantly decrease the likelihood that consumers will read the full claim.

In § 101.72(c)(2)(ii)(A) and (c)(2)(ii)(B), the agency is proposing requirements for the type size and location of the referral statement that are consistent with those for nutrient content claims in § 101.13(g)(1) and (g)(2).

FDA has long held that accompanying information should be in a size reasonably related to that of the information that it modifies. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. Section 403(r)(2)(B) of the act requires that a referral statement for nutrient content claims appear prominently, although it does not specify requirements such as to type size or style.

For nutrient content claims, FDA established type size requirements for referral and disclosure statements that are related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. The proportionality between size of the referral statement and the size of the label panel ensures that the referral statement is presented with appropriate prominence. However, when the claim is less than twice what the minimum size of the referral statement would be, given the size of the label and § 101.105(i), the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. This approach to the type size requirement for the referral statement provides additional flexibility to firms in utilizing label space but still ensures adequate prominence for this statement.

Because, under this proposal, health claim referral statements are to be used in a manner that is similar to how nutrient content claim referral statements are used, and because they are likely to appear on the principal display panel, the agency tentatively concludes that a health claim referral statement should be subject to the same type size requirements as those for nutrient content claims. Therefore, the agency tentatively concludes that the requirements for the referral statement set forth in § 101.72(c)(2)(ii)(A) and (c)(2)(ii)(B) are appropriate when an abbreviated health claim is used, and it is including them in this proposed rule.

In concert with the proposed requirements for an abbreviated health claim, the agency is including an abbreviated health claim among the examples of other model claims in proposed § 101.72(e).

E. Disclosure Versus Disqualifying Nutrient Levels for Health Claims

Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that ''does not contain, as determined * * * by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet.'' This section helps to ensure that consumers who rely on health claims will be consuming foods that will assist them in structuring a healthful diet that meets dietary guidelines.

As discussed more fully in the preamble to the 1993 health claims final rule, the agency implemented this provision by considering a food's role in the total daily diet and calculating levels of total fat, saturated fat, cholesterol, and sodium that would increase the risk of disease or health-related conditions in the general population. FDA calculated these levels by considering the number of foods consumed each day, as well as the number of foods that are likely to contain significant levels of these nutrients.

The agency has established different disqualifying levels for different types of foods, depending on the role that they play in the daily diet. Section 101.14(a)(5) defines the disqualifying level for individual foods as 20 percent of the DV's for total fat, saturated fat, cholesterol, and sodium. These levels

translate to 13.0 grams (g) of total fat, 4.0 g of saturated fat, 60 mg of cholesterol, and 480 mg of sodium per reference amount customarily consumed, per label serving size, and for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. The regulations make additional allowances for main dish products and meal-type products. The disqualifying levels for main dish and meal products are 30 percent and 40 percent of the DV, respectively. These different levels are consistent with the legislative history, which states, ''a particular level of fat in a frozen dinner might not trigger the provision, whereas the same amount of fat in a snack food might trigger it.''

A food that exceeds the disqualifying level for any of the four disqualifying nutrients may not bear a health claim unless the agency has granted an exemption ''based on a finding that such a claim would assist consumers in maintaining healthy dietary practices.'' (Section 403(r)(3)(A)(ii) of the act.) To date, the agency has received no petitions for an exemption from this provision.

The NFPA petition requested that the defined disqualification levels be converted to disclosure levels under certain circumstances. More specifically, the petition suggested that ''the presence of one of these nutrients at the prescribed level would require disqualification *only* if the nutrient was found in another health claim regulation to be directly and adversely related to the disease mentioned in the claim.'' The petition went on to state that ''[i]f the nutrient is not so directly related to the disease to which the claim refers, the regulations would require only disclosure by an appropriate referral statement in conjunction with the health claim on the label, as the regulations now require for nutrient content claims.''

As stated in the May 11, 1995, letter to NFPA, FDA concludes that a generic change in its regulations would not be consistent with the underlying goals of the NLEA. The current disqualifying levels assist consumers in constructing total daily diets that meet dietary guidelines. The agency considered the role a food plays in the daily diet when it calculated the disqualifying levels. Health claims on foods with levels of fat, saturated fat, cholesterol, or sodium that exceed the disqualifying levels would encourage increased intake of these foods and would make it difficult for consumers to follow the Surgeon General's recommendations and to construct a healthful diet. Even with the current disqualification levels, consumers could reach the DV's for total fat, saturated fat, cholesterol, or sodium by eating as few as five foods that bear health claims.

The agency considers the current disqualification rules to be consistent with congressional intent. Congress contemplated that health claims would be reserved for those foods that can contribute to a healthful diet. As the House Report states, ''Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet.'' (See H. Rept. 101–538, 101st Cong., 2d sess. pp. 9–10 (1990).)

Nevertheless, the agency tentatively finds that there may be some instances where disclosure rather than disqualification is appropriate. While FDA continues to believe that exceptions should be granted on a case-by-case basis, using a petition process, the agency recognizes that further guidance on the criteria that it will use to evaluate petitions for exceptions would be useful. FDA is, therefore, proposing to amend its regulations to give such guidance.

Proposed § 101.70(f) provides guidance for petitioners requesting an exception to the prohibition in § 101.14(e)(3) against health claims for foods exceeding the disqualifying levels identified in § 101.14(a)(5). This proposed amendment to the petition procedures sets out some of the factors that the agency will consider when evaluating a petition.

The first factor that FDA is proposing to list is whether the risk of the disease or health-related condition is of such public health significance, and the role of the diet so critical, that disqualification is not appropriate (proposed § 101.70(f)(1)). The agency recognizes that there may be instances where extraordinary efforts are needed to address a particular public health problem. In such cases, the agency would consider providing for disclosure rather than disqualification levels.

The second factor is whether the availability of foods that qualify for a health claim is adequate to address the public health concern that is the subject of the health claim (proposed § 101.70(f)(2)). The agency intends to consider whether the application of the claim is so limited because of the disqualification levels that it will not be possible to meet the public health goal of the health claim. If only a limited number of food products qualify to bear the claim because of the disqualifying levels, the agency would consider providing for disclosure rather than disqualification levels.

The third factor that FDA intends to consider is whether there is some evidence that the population to which the health claim is targeted is not at risk for the disease or health-related condition associated with the disqualifying nutrient (proposed § 101.70(f)(3)). Although the current disqualifying nutrients are associated with diseases or health-related conditions that pose risks to the general population, there may be some categories of foods that are targeted to specific subpopulations that are not at particular risk for the disease or health-related condition associated with the disqualifying nutrient (toddlers, for example). The agency would be willing to look at data and to consider whether an exception to the disqualifying levels should be made for foods intended for such subgroups.

Related to this criterion, is the question of whether there is evidence that consumers can identify themselves as being at risk for a particular disease or health-related condition associated with the disqualifying levels. For instance, some individuals can already identify themselves as being sensitive to sodium and, therefore, would recognize the risk of a high sodium food if it were disclosed. If the ability to self-identify for these risks becomes widespread, disclosure might be sufficient to reduce the risk from the disqualifying nutrient. FDA would expect to receive data that demonstrate that this ability exists, however, before it would be willing to grant an exemption on this basis.

Finally, the agency intends to consider whether there are any other public health reasons for providing for disclosure rather than disqualification (proposed § 101.70(f)(4)). The agency does not consider the above list of criteria exhaustive. There may be other criteria that would be useful in determining whether the agency should provide for disclosure rather that disqualification levels for health claims, and the agency is open to considering such factors.

The agency requests comments on the appropriateness of these criteria.

The agency notes that there are ways to convey important health information other than through health claims. A food may still be able to bear a nutrient content claim or a structure/function claim in order to highlight a particular attribute even if it exceeds the disqualification level for a health claim. For example, while whole milk may not be able to bear a calcium and osteoporosis health claim, it can still bear a ''high calcium'' nutrient content claim, so long as the levels of fat and saturated fat are disclosed. Similarly,

cooking oils that are lower in saturated fat may not be able to bear a ''healthy heart'' claim but can still bear a ''low'' or ''less'' saturated fat nutrient content claim.

In addition, some products can make other truthful and not misleading claims. For example, the label of whole milk can state ''Calcium builds strong bones.'' While such a claim is not considered a health claim under the 1990 amendments, it still conveys important dietary advice useful to consumers in constructing a healthful diet.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

FDA is proposing to: (1) Specify circumstances under which synonyms may be used, authorizing the use of unlisted synonyms provided that they are properly anchored to a listed term; (2) exempt certain types of products from the 10 percent nutrient contribution requirement; (3) provide the basis for shorter health claims by eliminating some of the required elements; and (4) permit an abbreviated health claim to be used on the principal display panel. FDA is also providing guidance for petitioners requesting an exception to the prohibition against health claims for foods exceeding FDA's defined disqualifying levels. The agency anticipates that the costs of this proposed rule will be minimal. If this rule is finalized as proposed, it will not require any manufacturers currently making claims to change their labels or labeling. Also, this rule may reduce the costs of making future claims by reducing the uncertainty and relaxing the requirements of the petition process for claims.

Although many health claims have appeared on a variety of products, the agency is concerned that health claims are not being used as extensively as they could be. To the extent that valid claims are not being used, a cost is imposed on society in that some valuable information may not be conveyed to consumers. This proposed rule will reduce the cost of lost beneficial information by making it easier for firms to make nutrient content and health claims. The agency is aware that the food label or labeling is a major means of providing information on foods at the point-of-purchase. By adopting a less restrictive approach to claims, the agency is providing industry with a method by which the label can be used to inform consumers of the health benefits of foods in such a way that will catch the attention of consumers. As long as the claims are truthful, not misleading, and scientifically valid, the additional information will benefit consumers by reinforcing the Surgeon General's recommendations and helping consumers maintain healthful dietary practices. In addition, the greater flexibility provided to industry will increase the incentive to develop more healthful products.

The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. The current claims regulations may have discouraged small businesses from making valid nutrient content claims and health claims. To the extent that this rule relaxes the restrictions on the ability of firms to use claims on the labels or in the labeling of their products, this rule will benefit small firms. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small businesses.

VII. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements; thus there is not ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule to permit additional flexibility in the use of health claims and synonyms for nutrient content claims on food labels imposes any paperwork burden.

VIII. Comments

Interested persons may, on or before March 20, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House Committee on Energy and Commerce, ''Nutrition Labeling and Education Act of 1990,'' 101st Congress, 2d sess., Report 101–538, pp. 9–10, June 13, 1990.

2. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, IOM, National Academy of Science, ''Nutrition Labeling, Issues and Directions for the 1990's,'' Washington, DC, National Academy Press, 1990.

3. United States Department of Agriculture, Human Nutrition Information Services, ''USDA's Food Guide Pyramid,'' Home and Garden Bulletin No. 249, April, 1992.

4. ''The Surgeon General's Report on Nutrition and Health,'' DHHS, Public Health Service Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

5. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy of Science, ''Diet and Health: Implications for Reducing Chronic Disease Risk,'' National Academy Press, Washington, DC, 1989.

6. National Institutes of Health, Office of the Director, ''NIH Consensus Statement, Optimal Calcium Intake,'' vol. 12, No. 4, June 6–8, 1994. Available from: NIH Consensus Program Information Service, P.O. Box 2577, Kensington, MD 20891, 1–800–644–6627.

7. Levy, A., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Market Studies, ''Summary Report on Health Claims Focus Groups,'' June 15, 1995.

8. Dietary Supplement Health and Education Act of 1994 (Pub. L. 103–417), October 25, 1994.

9. Technical Report—Cancer Prevention Awareness Survey—Wave II, Office of Cancer Communications, National Cancer Institute, National Institutes of Health, Bethesda, MD, November 1986.

10. Brenda Derby, Memorandum to Victor Frattali, ''Consumer Understanding of

Multifactoriality of Disease,'' October 25, 1995.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.13 is amended by revising the introductory text of paragraph (b) and adding new paragraph (r) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) A claim that expressly or implicitly characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling under § 101.9 with the exception of such claims on restaurant menus and except as noted in paragraph (r) of this section for unlisted synonyms, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

* * * * *

(r) Expressed synonyms for nutrient content claims may be used, provided:

(1) The term is listed as a synonym of a defined term in the regulations in subpart D of this part or in part 105 or part 107 of this chapter; or

(2) The term is used in a manner that complies with the following requirements:

(i) Such term is not misleading and, in the context of the entire label, is reasonably understood by consumers to be a synonym of a term listed in subpart D of this part or in part 105 or part 107 of this chapter;

(ii)(A) The term that is listed in subpart D of this part or in part 105 or part 107 of this chapter, and for which the unlisted term is being used as a synonym, appears prominently and conspicuously on the label, such that it is:

(*1*) Immediately adjacent (with no intervening material) to the most prominent use of the unlisted synonym (as determined in accordance with § 101.13(j)(2)(iii)); and

(*2*) At least half as prominent (including type size, style, and color) as the unlisted synonym authorized under this paragraph.

(B) If the term listed in subpart D of this part or in part 105 or part 107 of this chapter is more than twice as prominent on a label as the synonym authorized under this paragraph such that the claimed nutrient level is clearly understood (e.g., a claim in the statement of identity versus an unlisted synonym used only in a paragraph in small sized type), the term listed in subpart D of this part or in part 105 or part 107 of this chapter need not be placed adjacent to the unlisted synonym authorized under this paragraph.

(iii) The unlisted synonym is used in conformance with all the requirements for the use of the defined term, i.e., the referral statement required in § 101.13(g) and any other required label statements appear in the prescribed manner; and

(iv) This paragraph does not authorize a term listed in subpart D of this part or in part 105 or part 107 of this chapter to be used in conjunction with an unlisted qualifying term (e.g., ''extra low,'' ''extra high,'' ''especially good source,'' or ''great source'').

3. Section 101.14 is amended by revising paragraphs (d)(2)(iv) and (e)(6) to read as follows:

§ 101.14 Health claims: general requirements.

* * * * *

(d) * * *

(2) * * *

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear:

(A) The reference statement, ''See———— for information about the relationship between———— and ————,'' with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the name of the disease or health-related condition (e.g., ''See attached pamphlet for information about calcium and osteoporosis''), with the entire claim appearing elsewhere on the other labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material; or

(B) As authorized under subpart E of this part, an abbreviated claim consisting only of a truthful, nonmisleading, and scientifically valid description of the relationship between the substance and the disease or health-related condition, Provided that:

(*1*) Such an abbreviated claim is accompanied by a reference statement to the complete health claim;

(*2*) The reference statement is prominent and in immediate proximity to the abbreviated claim; and

(*3*) The complete health claim appears on the same label, or in the same labeling, in which the abbreviated claim appears.

* * * * *

(e) * * *

(6) Except for dietary supplements, fruit or vegetable products composed solely of fruits and vegetables, enriched grain products that conform to a standard of identity in part 136, 137, or 139 of this chapter, and bread which conforms to the standard of identity for enriched bread in § 136.115 of this chapter except that it contains whole wheat or other grain products not permitted under that standard, or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

* * * * *

4. Section 101.70 is amended in paragraph (f) by adding in the model petition new text immediately preceding the last undesignated paragraph of section B to read as follows:

§ 101.70 Petitions for health claims.

* * * * *

(f) * * *

B. * * *

In deciding the merits of a petition filed for an exception to the prohibition in § 101.14(e)(3) against health claims for foods exceeding the disqualifying levels identified in § 101.14(a)(5), the agency will consider the following factors:

1. The public health significance of the risk of the disease or health-related condition that is the subject of the claim and the role that the diet plays in decreasing that risk;

2. The availability of foods that qualify for a claim to address the underlying public health concerns;

3. Evidence demonstrating the population to which the health claim is targeted is not at risk for the disease or health-related condition associated with the disqualifying nutrient, including,

but not limited to, the ability of individuals to identify themselves as being at risk for the disease or health-related condition associated with the disqualifying nutrient; and

4. All other evidence demonstrating the public health need for waiving the disqualification requirements.

* * * * *

5. Section 101.72 is amended by revising paragraph (c)(2)(i); by redesignating paragraphs (c)(2)(ii) and (d)(2) as (c)(2)(iii) and (d)(5), respectively; by adding new paragraphs (c)(2)(ii), (d)(2), (d)(3), and (d)(4); and by revising paragraph (e) to read as follows:

§ 101.72 Health claims: calcium and osteoporosis.

* * * * *

(c)(2) Specific requirements. (i) *Nature of the claim*. A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim makes clear that adequate calcium intake as part of a healthful diet throughout life is essential to reduce the risk of osteoporosis. The claim does not imply that adequate dietary calcium intake is the only recognized risk factor for the development of osteoporosis;

(B) The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the population at particular risk for the development of osteoporosis as women in their bone forming years from approximately 11 to 35 years of age. An optional statement that further characterizes this and other populations at risk for developing osteoporosis may be made in accordance with paragraph (d)(3) of this section;

(C) The claim does not attribute any degree to which maintaining adequate calcium intake throughout life may reduce the risk of osteoporosis; and

(D) The claim states that total dietary intake of calcium greater than 2,000 milligrams (mg) per day (200 percent of the DV for calcium for adults and children 4 or more years of age or 154 percent of the daily value (DV) for pregnant or lactating women) provides no further benefit to bone health in reducing the risk of osteoporosis. This requirement does not apply to a food that provides 1,500 mg or less of calcium per day (150 percent or less of the DV for calcium for adults and children 4 or more years of age or 115 percent or less of the DV for pregnant or lactating women) when used as directed in labeling.

(ii) *Presentation of the claim*. All of the elements listed in paragraph (c)(2)(i) of this section must be included in one presentation of the claim displayed prominently on the label or labeling on which the claim appears. Other presentations of the claim on that label or labeling, including on the principal display panel, need not include the information in paragraphs (c)(2)(i)(B) and (c)(2)(i)(D) of this section provided that, displayed prominently and in immediate proximity to such claim, the following referral statement is used: ''See ———— for more information'' with the blank filled in with the identity of the panel on which is presented the statement of the claim that includes all of the elements in paragraph (c)(2)(i) of this section.

(A)The referral statement ''See [appropriate panel] for more information'' shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(B) The referral statement shall be immediately adjacent to any presentation of the health claim that does not include all of the elements of paragraph (c)(2)(i) of this section, and there may be no intervening material between the claim and the referral statement. If the abbreviated health claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the full health claim where it may be omitted.

* * * * *

(d) * * *

(2) The claim may list specific risk factors for osteoporosis, identifying them among the multifactorial risks for the disease. Such factors include a person's sex, age, and race. The claim may state that an adequate amount of exercise is also needed to reduce risk for the disease.

(3) The claim may further identify the population at particular risk for the development of osteoporosis as including white (or ''Caucasian'') women and Asian women in their bone forming years (approximately 11 to 35 years of age). The claim may also identify menopausal (or the term ''middle-aged'') women, persons with a family history of the disease, and elderly (or ''older'') men and women as being at risk.

(4) The claim may state that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase ''build and maintain good bone health'' may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss.

* * * * *

(e) *Model health claims*. The following are examples of model health claims that may be used in food labeling to describe the relationship between calcium and osteoporosis:

(1) *Examples 1 and 2*. Model health claims for a food that does not require the statement specified in paragraph (c)(2)(i)(D) of this section:

Especially for teen and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life.

A healthful diet with adequate calcium and regular exercise help teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

(2) *Example 3*. Model health claims for a food labeled for use by adults and children 4 or more years of age that requires the statement specified in paragraph (c)(2)(i)(D) of this section:

Exercise and a healthful diet with enough calcium may help teen and young adult women reduce their high risk of osteoporosis later in life. Adequate calcium is important for everyone (women and men at all ages) but daily intakes above 2,000 mg (200 percent of the DV) may not provide added benefit.

(3) *Example 4*. Abbreviated model health claim for use with a full health claim and that conforms with the requirements of paragraph (c)(2)(ii) of this section:

Adequate calcium in a healthful diet may reduce the risk of osteoporosis. See [appropriate panel] for more information.

6. Section 101.73 is amended by revising paragraphs (c)(2)(i)(F), (d)(1), and (e)(1) to read as follows:

§ 101.73 Health claims: dietary lipids and cancer.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(F) The claim does not imply that dietary fat consumption is the only

recognized risk factor for the development of cancer.

* * * * *

(d) *Optional information.* (1) The claim may indicate that development of cancer depends on many factors and identify one or more of the following as risk factors for the disease: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

* * * * *

(e) * * *

(1) A low fat diet may reduce the risk of some cancers.

* * * * *

7. Section 101.74 is amended by revising paragraphs (c)(2)(i)(E), (d)(1), (e)(1), and (e)(2) to read as follows:

§ 101.74 Health claims: sodium and hypertension.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(E) The claim does not imply that dietary sodium consumption is the only recognized risk factor for the development of high blood pressure.

* * * * *

(d) *Optional information.* (1) The claim may indicate that development of high blood pressure depends on many factors and identify one or more of the following as risk factors for the disease in addition to dietary sodium consumption: Family history of high blood pressure, growing older, alcohol consumption, and excess weight.

* * * * *

(e) * * *

(1) A low sodium diet may reduce the risk of high blood pressure.

(2) [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

8. Section 101.75 is amended by revising paragraphs (c)(2)(i)(E), (d)(1), (e)(1), and (e)(2) to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(E) The claim does not imply that consumption of dietary saturated fat and cholesterol is the only recognized risk factor for the development of coronary heart disease.

* * * * *

(d) *Optional information.* (1) The claim may indicate that coronary heart disease risk depends on many factors and identify one or more of the following in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

* * * * *

(e) * * *

(1) Diets low in saturated fat and cholesterol may reduce the risk of heart disease;

(2) Your risk of heart disease might be reduced by a diet low in saturated fat and cholesterol and a healthy lifestyle;

* * * * *

9. Section 101.76 is amended by revising paragraphs (c)(2)(i)(D), (d)(2), (e)(1), and (e)(2) to read as follows:

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(D) The claim does not imply that consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables is the only recognized risk factor for a reduced risk of developing cancer.

* * * * *

(d) * * *

(2) The claim may indicate that development of cancer depends on many factors and identify one or more of the following as risk factors for the disease: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

* * * * *

(e) * * *

(1) Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer.

(2) A diet low in fat and high in grain products, fruits, and vegetables that contain fiber may reduce your risk of some cancers.

* * * * *

10. Section 101.77 is amended by revising paragraphs (c)(2)(i)(F), (d)(1), and (e) to read as follows:

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(c) * * *

(2) * * *

(i) * * *

(F) The claim does not imply that consumption of diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, is the only recognized risk factor for a reduced risk of developing coronary heart disease.

* * * * *

(d) *Optional information.* (1) The claim may indicate that development of coronary heart disease depends on many factors and identify one or more of the following as risk factors for the disease: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

* * * * *

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber and the risk of coronary heart disease:

(1) Diets low in saturated fat and cholesterol and rich in fiber-containing fruits, vegetables, and grain products may reduce the risk of heart disease.

(2) A diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

11. Section 101.78 is amended by removing paragraph (c)(2)(i)(D); by redesignating paragraphs (c)(2)(i)(E) through (c)(2)(i)(J) and (d)(3) through (d)(5) as (c)(2)(i)(D) through (c)(2)(i)(I) and (d)(4) through (d)(6), respectively; by revising newly redesignated paragraph (c)(2)(i)(I), paragraphs (d)(2), (e)(1), and (e)(2); and by adding new paragraph (d)(3) to read as follows:

§ 101.78 Health claims: fruits and vegetables and cancer.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(I) The claim does not imply that consumption of diets low in fat and high in fruits and vegetables is the only recognized risk factor for a reduced risk of developing cancer.

* * * * *

(d) * * *

(2) The claim may indicate that development of cancer depends on many factors and identify one or more of the following as risk factors for the disease: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may characterize fruits and vegetables that meet the requirements described in paragraph (c)(2)(ii) of this section as foods that are low in fat and that contain (or are a good source of) one or more of vitamin A, vitamin C, or dietary fiber.

* * * * *

(e) * * *

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A and vitamin C), may reduce the risk of some types of cancer.

(2) A diet low in fat and high in certain fruits and vegetables, foods that are low in fat and that may contain vitamin A and vitamin C, may reduce your risk of some cancer.

Dated: December 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–31008 Filed 12–20–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N–0176]

Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting certain statements in the preamble to a proposed rule that appeared in the Federal Register of October 4, 1995 (60 FR 51946). The document proposed to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. The document states further that FDA is issuing for public comment the recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) concerning the classification/reclassification of pedicle screw spinal systems, and the agency's tentative findings on the Panel's recommendations. The document is being corrected to reflect an accurate description of the formation, membership, and activities of the Spinal Implant Manufacturers Group (SIMG), and the Scientific Committee, two separate entities established by the spinal implant manufacturers and medical professional societies to collect and submit to FDA all available valid scientific data on the performance of pedicle screw spinal devices.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

In the FR Doc. 95–24686, appearing on page 51946 in the Federal Register of Wednesday, October 4, 1995, the following corrections are made:

1.On page 51947, in the second column, in the fourth paragraph, beginning in line 7, the second, third, and fourth sentences are removed and the following text is added in their place to read as follows:

In response, two groups were founded: The Spinal Implant Manufacturers Group (SIMG), and the Scientific Committee. SIMG, founded by 16 medical device manufacturers, agreed to provide the funding that would be required to conduct a nationwide study of pedicle screw devices. The Scientific Committee was formed by five professional medical societies, including the North American Spine Society, the American Academy of Orthopedic Surgeons, the Scoliosis Research Society, the Congress of Neurosurgeons, and the American Association of Neurological Surgeons. The Scientific Committee was formed to develop and implement a uniform research protocol to gather clinical experience from the use of the device. The Scientific Committee consisted of four surgeons and two nonvoting SIMG representatives, a biostatistician, and a clinical/regulatory affairs professional.

2. On page 51947, in the third column, in the first paragraph, beginning in the fifteenth line, the fourth and fifth sentences are removed and the following text is added in their place to read as follows:

At this meeting, the Scientific Committee presented clinical data from its nationwide ''Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusions'' (Cohort Study). FDA presented a comprehensive review of the medical literature, an analysis of the medical literature, an analysis of the Cohort study conducted by the Scientific Committee, and a summary of the clinical data that had been released by IDE sponsors.

3. On page 51950, in the first column, in the fourth paragraph, in the first line, the abbreviation ''SIMG'' is corrected to read ''Scientific Committee''.

Dated: December 8, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95–31047 Filed 12–20–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[INTL–52–86]

RIN 1545–AL99

Statements to Recipients of Dividends and Patronage Dividends

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of a notice of proposed rulemaking.

SUMMARY: This document withdraws a portion of the notice of proposed rulemaking under sections 6042 and 6044 of the Internal Revenue Code that was published in the Federal Register on February 29, 1988, as proposed to be amended on September 27, 1990. The proposed regulations prescribed rules for official statements to recipients of dividends and patronage dividends paid after December 31, 1983.

DATES: This withdrawal is effective on December 21, 1995.

FOR FURTHER INFORMATION CONTACT: Renay France, (202)622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On February 29, 1988, the IRS issued proposed regulations on backup withholding (INTL–52–86, 53 FR 5991). The proposed regulations related, in part, to official statements to recipients of dividends and patronage dividends under sections 6042 and 6044, respectively (proposed §§ 1.6042–5 and 1.6044–6). On September 27, 1990, the IRS issued additional proposed regulations on backup withholding (IA–224–82, 55 FR 39427). Those proposed